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UNOFFICIAL TRANSCRIPT*
WASHINGTON STATE
PHARMACY AND THERAPEUTICS COMMITTEE MEETING

June 16, 2010
Sea Tac Marriott Hotel
9:00am – 4:00pm

Vyn Reese:	Good morning. This is Dr. Reese and I want to welcome everyone to the Washington State Pharmacy and Therapeutics Committee meeting. Let's start first with introductions. I'll begin on my left.
Thad Mick:	Thad Mick with the ODS Companies.
Amy Irwin:	Amy Irwin from Washington Medicaid.
Chuck Agte:	Chuck Agte, Washington Medicaid.
Cathy Williams:	Cathy Williams, Board of Pharmacy.
Jaymie Mai:	Jaymie Mai, Labor and Industries.
Doug Tuman:	Doug Tuman, Labor and Industries.
Jeff Graham:	Jeff Graham, Health Care Authority.
Deb Wiser:	Deb Wiser, Committee Member.
Christine Klingel:	Christine Klingel, Committee Member.
Susan Rowe:	Susan Rowe, Committee Member.
Vyn Reese:	Vyn Reese, Chair.
Carol Cordy:	Carol Cordy, Committee Member.

* For copies of the official audio taped record of this meeting, please contact Regina Chacon at (206)521-2027 pdp@hca.wa.gov.

Barak Gaster: Barak Gaster, Committee Member.

Jason Iltz: Jason Iltz, Committee Member.

Alvin Goo: Alvin Goo, Committee Member.

Regina Chacon: Regina Chacon, Health Care Authority.

Leta Evaskus: Leta Evaskus, Health Care Authority.

Donna Sullivan: Donna Sullivan, Health Care Authority.

Duane Thurman: Duane Thurman, Health Care Authority.

Jeff Thompson: Jeff Thompson, Washington State Medicaid.

Ray Hanley: Ray Hanley, Health Care Authority.

Nancy Fisher: Nancy Fisher, Health Care Authority.

Margaret Dennis: Margaret Dennis, Health Care Authority.

Phyllis Wene: Phyllis Wene, Department of Corrections.

Vyn Reese: Okay. Thank you. Jeff, are there any announcements today?

Jeff Thompson: Maybe Duane has some. I don't.

Vyn Reese: Duane?

Duane Thurman: Yeah. This is Duane Thurman. Just an update. We…the new budget takes effect July 1st and we now have directives that really limit our ability to (1) have meetings in public…in private facilities. It has other ramifications in terms of travel reimbursement, our ability to contract, all of that. And so we're working through the governor's budget office to figure out what exactly we're going to do. So I guess the most relevant thing for this committee is we're unclear where we're going to have our next meeting. We have a meeting in October and December and then we have three more next year. The ban is supposed to go away in the middle

of next year but looking at the budget I don't anticipate that. So just a heads up for everybody that…with our next meeting notice we may not be having it at this room. We are trying to make the case that we do have certain needs and try to make it…explain it may not be cheaper to have everyone rent a car and drive to Olympia. So I would suggest you enjoy the coffee and tea today. It may be the last time we have refreshments. But I will make sure that as soon as we resolve the issue we let you know where the facility is and I will try to make sure that we have everything we need to continue to have successful meetings. So that's the first news.

Vyn Reese: Thank you Duane. We'll look eagerly at our emails to see where we meet next. Is Kim Peterson online?

Kim Peterson: Yes I am. Good morning.

Vyn Reese: Okay. Our first slide is up. It's the drug class review on calcium channel blockers. Why don't you go ahead.

Kim Peterson: Okay. Well I'll be presenting results from the fourth preliminary update scan of this review. Let's go on to slide #2 and I'll start by reminding you of the history on this review. This one was last fully updated in March of 2005. So sorry about the error on the slide. That second line should say March 2005 not March 2009. So it is outdated and since then the drug effectiveness review project has conducted three preliminary update scans and each time has decided against a full update. And then actually in April of this year the drug effectiveness review project participating organizations finally decided to actually archive this review. So it will no longer be…we will no longer be considering it for updating at all in the future. So this preliminary update scan that the Oregon Evidence Based Practice Center performed commissioned entirely by your program for the sole use of your program. So that's the history on this review. Let's go on to the next slide.

So the next few slides outline the inclusion criteria. So for populations we included adults with hypertension, angina, supraventricular arrhythmias or supraventricular tachycardia and/or systolic dysfunction. That being defined as left ventricular ejection fraction less than 45%. And then for interventions we included oral forms of benign calcium channel blockers listed on this slide. Let's go on to slide 4.

Where we have the included outcomes for effectiveness and efficacy outcomes we primarily focus on all cause mortality, cardiovascular disease, mortality, cardiovascular events, and quality of life across all the populations and then there were also some other population specific outcomes that were included that are

included in the scan report. And then we have included the usual harms outcomes that we always include in our reviews. So let's go on to slide 5.

So now we're getting into the results of the scan starting with the searches of the FDA and Health Canada websites. We actually did not identify any new calcium channel blockers and we did not find any information on any new indications or new black box warnings for any of the previously included calcium channel blockers. Next slide.

Here's the details of our literature search. To identify new potentially relevant controlled clinical trials we searched Medline starting in April of 2009, which was the cutoff date of the last preliminary update scan through May of 2010. And then a new thing we're doing is…started last month I think. We're going to be searching the websites of the Agency for Health Care Research and Quality and also the website of the Canadian Agency for Drugs and Technologies in Health to identify new comparative effectiveness reviews that have been completed since the time of our last update. So among the…I think six scans you're going to be presented today a few of those have used this new process and this is one of them. Let's go on to the next slide.

And here's the results of our literature search, which were very sparse. The only new potentially relevant literature we found was a sub analysis of cardiovascular event rates from the previously included CASE-J trial, which was a comparison of cadesartan and amlodipine. Otherwise we actually found no new trials and we also found no new comparative effectiveness reviews. And so although we found almost no evidence for this scan we do have a note that there are an additional 40 publications that we had identified in the previous three scans and for your convenience we provided the abstracts of those publications in the full scan report. But again the majority of those were sub analyses of previously included trials and non were head-to-head trials, which has always been lacking for this review. So let's go to the next slide, which is the last slide. So I'll turn it back over to you for discussion.

Vyn Reese: Okay. Thank you. I'll take a motion from the committee to accept the scan.

Carol Cordy: This is Carol Cordy. I make a motion to accept the scan.

Vyn Reese: And a second?

Susan Rowe: Susan Rowe, I'll second the motion.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. I'll open it up for questions from the committee. Are there any questions for Kim Peterson? Nope. Okay. Any stakeholder input on this drug class? No one is signed up. So discussion and motion if there's not a…doesn't look like there's a lot going on in this class. Is there any further discussion?

Carol Cordy: This is Carol Cordy. I just have a question since this is going to be archived, you said. What does that mean for us?

Vyn Reese: Kim, are you still there?

Kim Peterson: I am. Um, but I think that would be a question for your committee. What it means for the drug effectiveness review project…this is a new process where it's decided that reviews just will not…they will be archived and they will not be considered for any future updates. It just means that our reports will really not…I don't know how useful it will be as time passes and so I, you know, so you have commissioned this preliminary update scan on your own and you could continue to do that. But for the drug effectiveness review project we won't be conducting anymore preliminary update scans and it won't be updated in the future most likely.

Duane Thurman: This is Duane Thurman. What we need to decide is how to keep doing this and we do have several drug classes that were unique to Washington State and we've retained the project to continue to do updates on those and so I think when it comes to the next time for review of this class we will ask you if you want us to go forward with an independent review to continue that. And then the question will be whether we have sufficient budget to do that and so our intention is to continue our process even if we have to contract separately.

Vyn Reese: This is Dr. Reese. It sounds like in this case this is a pretty static class and I think probably we don't need to spend the money…scan, especially if it's being archived. So my bias would be that we didn't look at this group again unless there's some major new development.

Duane Thurman: Right. And I think we're going to see that in several drug classes as our program moves apart from what the whole DERP project is reviewing. I see that as sort of the next phase how we maintain our effort to get what you need before you.

Vyn Reese: And not do needless reviews that…where there's not any new data essentially. That's the other side of the question.

Duane Thurman: Right, right. I mean that was partially how we came up with the scan process and so now we're looking at what we do…we update scans and then something else. So we'll be working on that.

Vyn Reese: Great. Thank you. Let's look at the motion now.

Barak Gaster: This is Barak Gaster. I move that we reiterate the motion that we passed on June 17, 2009.

Vyn Reese: This is Dr. Reese. Is there a second?

Alvin Goo: This is Alvin Goo. I second.

Vyn Reese: All those in favor say, "Aye".

Group: Aye.

Vyn Reese: Opposed, same sign. The motion has passed. Let's go on now to the next drug class. This is the drugs to treat over active bladder. We'll get our slides up and then we can proceed.

Kim Peterson: Okay. Sorry. Did you say you have your slides up?

Vyn Reese: Just a second. Just give us a minute to get them up. They're on the way.

Chuck Agte: This is Chuck Agte. I actually have a quick question on the calcium channel blockers.

Vyn Reese: Sure.

Chuck Agte: Is there a reason bepridil is highlighted? Is that a new addition to the list? Because I thought there was a calcium channel blocker out there that doesn't share all the same indications as the rest of the class. I wanted to make sure that's not the one that was left off purposely before.

Kim Peterson: Is that a question for me? Where is it highlighted?

Chuck Agte: It's not in your slides. It's in our previous motion list.

Kim Peterson: Oh, okay. So it's a question for you. I don't know why it would be highlighted. Did it go…it's occurring to me that…did it…was it discontinued? Was the manufacturing of it discontinued?

Donna Sullivan: Chuck, this is Donna Sullivan. It was highlighted because it was not in the previous motion.

Kim Peterson: Oh, okay.

Donna Sullivan: So we'll handle that outside of the meeting if it's…if we didn't include that drug for that reason then we won't include it again.

Kim Peterson: Okay.

Vyn Reese: Okay. Let's go on now to the drug class review on agents for over active bladder.

Kim Peterson: Okay. So here…I'm going to be presenting the results from the first preliminary update scan of our UN agents for overactive bladder that we performed back in February of this year for the DERP participating organizations consideration of a fifth update on this review. So let's go on to the next slide.

Which lists the most recent activity on this review, which was the completion of the fourth full update in March of 2009. So this report is relatively recent. Let's go on to slide 3.

So the next few slides list the inclusion criteria from the last update and for populations we included adult patients with symptoms of urge, incontinence and over active bladder. So the symptoms of urgency, frequency, leakage and dysuria. And then for interventions we included the eight drugs that are listed on this slide. Let's go on to slide 4.

For effectiveness outcomes we included change in the mean number of incontinence episodes, micturitions and pads per 24 hours. And subjective patient assessments and symptoms as well as quality of life and then we included the usual harms outcomes. Next slide.

So now for the results of the scan starting with the searches of the FDA and Health Canada websites for information on new drugs, new indications and new safety alerts. So while we didn't find any information on new indications and new safety alerts for any of the previously included overactive bladder drugs we actually did identify two new overactive bladder drugs. Those being Gelnique which is a transdermal gel formulation of oxybutynin, which was approved back in January of 2009 and then the new oral drug fesoterodine which was approved in October of 2008. Next slide.

Now on to the results of our new…of our search for new literature. So this is one where we hadn't started the process of searching for new comparative

effectiveness reviews yet. So we were only searching for…only searched Medline starting in December 2008 which was the search cutoff date for the last full update and through February of 2010 and found a total of 77 new citations. Next slide.

And of those we found a total of 13 new potentially relevant trials which included three head-to-head trials, two of which compared the new oral overactive bladder drug fesoterodine to tolterodine and we also found…for placebo-controlled trials we also found one that evaluated fesoterodine as well as one that evaluated the other new drug, the Oxybutynin and transdermal gel. Next slide.

So that concludes the summary of the findings from our scan. Note here that based on this scan even though there were two new drugs and some studies on the new drugs, the drug effectiveness review project participating organizations voted against a full update of this review. So the evidence-based practice center has not fully evaluated the trials identified in the scan and the next time that this review will be considered for a full update is estimated for February of 2011. So now I'll turn it back over to you for discussion.

Vyn Reese: Thank you. This is Dr. Reese. I'll take a motion to accept the scan.

Barak Gaster: This is Barak Gaster. I move that we accept the scan.

Vyn Reese: This is Vyn Reese. I'll second that. All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. Are there any questions from the committee on this drug class? There is stakeholder input. The first speaker…I want to remind you that you have three minutes to speak and that will be timed. The first person on the agenda is Leigh Platte from Astellas. And on deck is William Brunkhurst from Pfizer.

Leigh Platte: Good morning. I'm Leigh Platte from Astellas Pharm. I'm a Scientific Liaison and I'm here today to talk about VESIcare. VESIcare is indicated for the treatment of overactive bladder with urge, incontinence, urgency and frequency. It was evaluated in four phase three and five phase four randomized controlled trials. In three open label trials investigating efficacy and key overactive bladder symptoms and patient reported outcomes. VESIcare can increase the warning time, the time from first sensation of urgency to voiding and reduce episodes of urgency and severe urgency [inaudible] from the [inaudible] trial.

A 12-week randomized double blind, placebo-controlled study of VESIcare 5 and 10 measuring change and urgency episodes per 24 hours as the primary end point. VESIcare can improve patient reported outcomes for overactive bladder symptom, bother and other quality of life domains. From the Vibrant study another 12-week randomized double blind, placebo-controlled flexible dose study assessing change in patient reported outcomes. The primary endpoint was symptom bother reported on the OABQ and included other health-related quality of life assessments.

VESIcare demonstrates significantly fewer dry mouth episodes and significantly less dry mouth severity as compared to oxybutynin immediate release from the Vector study which compared the tolerability and efficacy of 5 mg of solifenacin once daily with 5 mg oxybutynin immediate release three times daily.

And finally VESIcare produced no clinically meaningful changes in mean heart rate or mean blood pressure from a German study. A 12-week open label, post marketing surveillance study of 4,146 overactive bladder patients treated with VESIcare found [inaudible] clinically meaningful alterations in mean heart rate or mean blood pressure from baseline to end of study. The most common emergent AEs across all studies included dry mouth, constipation, blurred vision, dry eye and headache. And please refer to the prescribing information for more extensive information from the pivotal trials.

In summary, VESIcare consistently demonstrated significant improvements in diary based overactive bladder based symptoms. Patient reported subjective assessments and favorable tolerability across several safety parameters. Thank you. Any questions?

Vyn Reese: Thank you. Are there questions from the committee?

Leigh Platte: Thank you very much.

Vyn Reese: Thanks. Next speaker is William Brunkhurst from Pfizer.

William Brunkhurst: Good morning. I'm Bill Brunkhurst. I'm the Account Manager for Pfizer Pharmaceuticals and I'd like to address the two studies that were cited by the drug effectiveness review project in regards to Toviaz and Detrol LA. In presenting this information there were two recently completed clinical trials which prospectively compared the efficacy and safety of Toviaz 8 mg a day to Detrol LA 4 mg a day in adult patients with overactive bladder. These two similarly designed studies were 12-week randomized trials, excuse me, excuse me, placebo-controlled multi-center head-to-head superiority trials and within the two studies there were over 4,000 patients treated with either Toviaz, Detrol or a placebo. All patients in the Toviaz group started on Toviaz mg for one week

followed by a dose increase to 8 mg for the ensuing 11 weeks. The highest recommended dose for Toviaz is 8 mg, the recommended dose for Detrol in the study was 4 mg. The primary endpoint of these two studies was a change in the mean number of urgency, urinary, incontinence episodes per 24 hours from baseline to week 12. In both trials 4,000 patients Toviaz 8 mg was superior to Detrol LA 4 mg in reducing UUI episodes for the 12-week, 24-hour relevance. In both studies the Toviaz and Detrol LA treatment groups had similar emergent treatment adverse reactions and in summary there are now two large prospective designed placebo-controlled, head-to-head trials that demonstrate Toviaz 8 mg as being superior to Detrol LA 4 mg in reducing UUI episodes.

I bring this up as a relevance in the past four years as I've watched the committee address OAB products. They've all been considered to be equal in efficacy. We now have 4,000 patient trials that show that Toviaz is more efficacious than what had been considered a gold standard in [inaudible] being Detrol. An questions, please?

Vyn Reese: Thank you. Any questions from the committee? Okay. And that's the last speaker. Let's open this for discussion.

Patti Varley: This is Patti Varley. I just have a question for the committee as a whole. Did anybody else get material sent to them about this medication group?

Group: Yeah.

Vyn Reese: Yeah. With the review.

Patti Varley: The reason I'm asking is that I thought it was a joke from a colleague because I'm a middle aged woman. So I didn't think about it being related to this committee until just this second. And if we've all received material we need to instruct people on how to appropriately give this committee material. It should not be sent personally to our…

Vyn Reese: I don't know what material you're talking about. I thought you were talking about committee-related material.

Patti Varley: No. I got…

Vyn Reese: What did you get?

Patti Varley: Did you get it? Maybe it was just directed to the women. We got…because I really just thought about it and I think…there is an appropriate way to get material to the committee members, but I actually had thought until this moment that it was a colleague in my office who sent it to me as a joke. And if some of

the rest of us were also sent material directly then…oh, even the men. Okay. Then I think we just need to educate the manufacturers about how to appropriately get material to us, which is not personally directed. Is that correct?

Duane Thurman: This is Duane Thurman. Our protocol is that all information that will be considered by you should be submitted to the DERP project directly. You can send it to Jeff Graham, myself, Regina Chacon and we will get that to them. I mean obviously you're going to come across information in your normal practices, but for our purposes we do require that everything do go through the DERP project.

Patti Varley: Thank you.

Vyn Reese: I have a question. This is Dr. Reese again. We always have this come up and I want to talk to the agencies about what do we do when we have two new…one new drug and one new transdermal product, which is a different way of administration. This comes up every time we do a scan and I want to just review that with the agencies. How do we handle this and do we add this onto the list because they have positive studies or how are you handling it.

Donna Sullivan: This is Donna Sullivan. Since this was a scan update and not a full update they would not be considered part of the class. So they would be handled as each agency handles all of the drugs that are not part of the PDL process.

Vyn Reese: Any other comments about that?

Duane Thurman: This is Duane Thurman. Just to add to that, the whole purpose of the scan is to try to provide you with enough information to make the decision you feel comfortable with. The one thing that we haven't done to this point is at some point we expect you to say the scan is not adequate and we need a full update of the class. And so that is an option we could do. You could suspend it and see if we can reach a contract to get a Washington only full update rather than a scan. If you believe that there's enough information in the scan to make a decision I think it's within your authority to do that. But I think we're really…I think if you're going to include the new drugs, if they are significantly different, we would need to do a full updated review for you.

Vyn Reese: If I was an endorsing prescriber and I want to prescribe one of the new drugs I would be able to prescribe them or it would have to be…

Duane Thurman: It would be as though this program didn't exist. So there might be prior authorization requirements for Medicaid. There may be different co-pay tiers for the other programs. But it's sort of a…it would not fall under the endorsing, non-endorsing system.

Vyn Reese: Okay.

Duane Thurman: You could write "dispense as written". Even if you're an endorser you may have to still go through PA.

Man: And nor would it be subject to TIP.

Duane Thurman: Right. And it would not be subject to TIP.

Vyn Reese: Any other discussion?

Susan Rowe: This is Susan Rowe. I do have a question on those…the two studies that are representative from Pfizer…sited. I…looking at clinicals and statistical significance versus really practical significance I would like to know the actual number of decrease of the number of times the patients had to go up and go to the bathroom. And if that made a difference practically or did it just fall into that statistical significance?

William Brunkhurst: Are you asking me?

Susan Rowe: I am.

William Brunkhurst: Could I actually get the studies to you because I don't have that actual specific information to you and I can deliver that and then I can answer that question and subsequent ones that come up?

Susan Rowe: Okay. That's fine.

Duane Thurman: Um, one last comment from Duane. I know that the evidence…he's brought it to you today but the proper way is to submit that to the DERP project and have them ask the questions that you're asking and put that into the report that we may or may not request.

Susan Rowe: Can you submit it to the DERP project, please.

William Brunkhurst: I'll do that also.

Susan Rowe: Thank you.

Carol Cordy: This is Carol Cordy. If I heard you right this is going to be up for a complete update in February. Is that right?

Kim Peterson: That's an estimated date. That would be a year from…usually the DERP project usually considers…now that we've decided that we can…it's not an automatic…we don't automatically conduct scans on an annual basis. Now we pose the question to the participating organizations as to whether they'd like to conduct a scan or not. And that process will occur likely in February of 2011.

Carol Cordy: So it may or may not…

Kim Peterson: There's no longer a guarantee even that a scan will occur. But I would guess for this class that probably the group would be interested in conducting the scan because there are these two new products that haven't been included yet.

Jeff Graham: Kim, this is Jeff Graham. Even if we considered doing a scan and did a scan that doesn't guarantee that a full update will be done.

Kim Peterson: That's absolutely right. Yeah. So there's like two steps to deciding whether or not an update will occur now.

Duane Thurman: This is Duane. The bottom line is do you want us to request an update to this drug class? And if so we will try to work through our budget and find out what it would take to achieve that beyond just a scan. Because a scan will not address the additional new drugs in the class. I guess the best thing to do is probably to see what the group does and to report back to you in terms of what they intend to do. It may resolve itself. If not we could try to move forward on our own update.

Vyn Reese: This is Dr. Reese. They're going to decide that in February whether they are going to do a scan or an update. Is that correct?

Duane Thurman: Yes.

Vyn Reese: I mean the drugs in this group they're different delivery systems now that you might want to use in a special circumstance and you might want to have those available to you. And somebody who could have difficulty swallowing or something like that. I mean I could see ways that we might want to have the availability to prescribe these drugs. It's a close call and I'm not sure what DERP is going to decide. And there's a new drug too. It's a borderline situation. We'll see what they decide. We may want to go for a full update if they don't want to, but I'd like to see what the review process is.

This is Dr. Reese and I wanted to ask the reviewer again, how do you decide whether you're going to do a complete update versus a scan? I mean what are your criteria?

Kim Peterson: Well the decision is actually…there are no criteria and it's a very flexible process and the decision is actually entirely based on, you know, the majority voting…it's a voting process by the participating organizations. So…just based on majority rules. So our, you know, the Oregon EPC doesn't actually contribute to the decision of whether or not a review is going to be updated.

Patti Varley: This is Patti Varley. So it sounds like from listening, Vyn, to what you said and from listening to what she said and what Duane said that we could say that we…we would request if possible a full review because of these issues of these new medications and they would take that into consideration and see if within the restraints and budget, etc. that could be done. And I think that…in this case what we're saying is the scan did not include some of the new medications and the new forms of medications that are now available. So it's hard for us to have the same kind of information we normally would get from a full review.

Vyn Reese: Right.

Kim Peterson: Right. In the scan I did identify those new studies but, you know, within the scan process our charge is only to identify those studies. So we only provide the abstracts of those. So to be able to fully assess the internal validity and the nuances of the…the clinical relevance of the outcomes such as were being inquired about that does…that falls outside of the restraints of the scan process and would require full updates.

Duane Thurman: This is Duane. Um, I'm sorry this is so complicated. I guess what we're seeing is the evolution of our preferred drug list and I guess from Washington State's perspective what we're seeing is that, you know, the output from DERP is used by many states in different ways. And so I think as we move forward we're going to have more individual issues that the group will not be able to agree on. But I think I can summarize that…and Jeff you'll take notes on this that we will ask for an updated review of this. It's our position that when there are new class…drugs added to the class that we do need to do an updated review at the least, if not a full drug class review. And so to the extent that our vote does not carry then we'll come back and get your impression as to what…how you'd like us to move forward with an updated scan…I mean an updated review, a full review and then we have to work through to convince the legislature that our process is evolving and that we…instead of bringing on new drug classes we're having to bear the cost of reviewing these independently for Washington state. So we'll see what happens in February and report back.

Barak Gaster: This is Barak Gaster. I just wanted to do a quick clarification of something that Vyn Reese said. He was concerned that…wanted to make sure that new drugs were available to prescribers. I just want to clarify that new drugs are still fully

available to prescribers to prescribe they just won't be subject to the therapeutic interchange.

Duane Thurman: Correct. Correct.

Vyn Reese: You'll also go through a review process basically. You'll have to document your reasons for prescribing that drug over another drug that's on the preferred drug list.

Duane Thurman: Drugs that are not on the preferred drug list basically pretend like this program never existed. You can prescribe like you did back then.

Barak Gaster: Right. So I mean…Barak Gaster again. So issues…I mean so this…whether or not the new drugs are included in a review or not doesn't impact the issue of whether there is a prior authorization needed. And so that…and so to me sort of understanding that issue better makes it less sort of a compelling urgency that we have a new complete review when a new drug is added.

Duane Thurman: Right. I mean there are hundreds of drug classes that are not on our preferred drug list and those are prescribed in the way that they always have been. So they are available. There may be different administrative burdens to prescribe them.

Vyn Reese: I think Barak what you may not know is that if you do prescribe that you will have to…you will have to…it will have to go through channels to be…to get it okayed depending on which agency you're prescribing it in. So it's going to be reviewed and you're going to have to…it won't be a prescription that goes through immediately. It's going to be something that's going to be reviewed. You'll have to give your reasons for prescribing it and the patient will wait to get it done until the agency approves that. Is that correct?

Barak Gaster: But isn't that…Barak Gaster again. Isn't that process separate from the preferred drug list?

Duane Thurman: Yes. This is Duane. The way it's going to work is, you know, basically in general at the commercial plans…Uniform Medical Plan it's the tier that you pay. In Medicaid it's a possibility of some sort of a prior authorization. So it's going to vary by program. But yes it's available just like it was.

Patti Varley: This is Patti Varley. Just a point of clarification as far as cost benefit and financial responsibility. I'm just curious; if we start to recognize as we evolve that some of these scans are unnecessary because there's nothing new so rather than rescanning things as we just talked about in the earlier class. Um, will that offset some of the costs that we then say when we have a class like this where we are recommending a review because there are new drugs. I mean I'm wondering

is that part of the evolution too of where the dollars will flow to be more appropriate to what is needed?

Duane Thurman: This is Duane. I guess that's something that I'd prefer the committee not engage in. Our position is that we have to do what is transparent and accurate and to the extent the scans are relatively inexpensive and the point there is we want to do our due diligence to make sure we've seen any new research that comes out so that when we're making a…when you're making a determination at least you're doing it on the basis of what's out there. So I think the recent issue is, does the legislature want to continue to support what's been a very successful program in terms of really trying to say we're not going to cut corners on, you know, we need to look at evidence and we need to pay to get that evidence put together. So that is my job to continue to communicate that to the decision makers.

Jeff Graham: This is Jeff Graham and I just want to say that the DERP participating organizations are dealing with this issue right now. What do we do when a new drug appears in a class that we're not really sure what kind of impact that would have and how to look at that drug without having to do a really full update on every single study that's been done. No decisions have been made but we are trying to come up with some type of policy to work through that, which would sort of meet sort of some of the issues we're talking about right now.

Jason Iltz: This is Jason. I just wanted to sort of reiterate that with this drug class…I mean I don't have the foresight to know how the agencies would handle it, but Vyn you mentioned too that a unique delivery mechanism is going to have a niche in a very small population. My thought would be that that may be subject to some sort of prior authorization or expedited review anyway in order to get the use of a patch approved even if it was on the PDL.

The other thought is as I look at this class there are a number of other agents that are available and on the PDL that could be tried prior to moving to one of the other review processes. So I guess that's one of the things as I look at it's not like we only have one or two agents to choose from and we're really limited it at least from a starting point. So my thought would be that as we look at this we…I would make the motion that we reiterate the motion from June 17, 2009 for this particular drug class.

Vyn Reese: Okay. Thank you. I'll have a second on that.

Barak Gaster: This is Barak Gaster. I second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Let's move on to the next drug class. And the next drug class can is the antiemetics.

Kim Peterson: Yes. Do you have your slides up?

Vyn Reese: Wait just a sec. We're still working on the slides. There you go. They're up now. Thank you.

Kim Peterson: Okay. So these are the results from our preliminary update scan of our review on newer antiemetics. We performed the scan back in December of 2009 for consideration of the second full update of this review. Next slide.

So this slide lists the most recent activity on the review which was the completion of the first full update in January of 2009. Next slide.

The new few slides list the inclusion criteria and for populations we included both adults or…and children at risk for or with nausea, vomiting or both related to chemotherapy, radiation therapy, surgical procedures and pregnancy. And for interventions we included both the oral and intravenous formulations of the four 5HT3 antagonists and well as aprepitant and fosaprepitant [inaudible] formulation. Next slide.

So here's the included outcomes and for effectiveness we focused on the outcomes of no vomiting and the…and composite outcomes of no emetic events. The most commonly…the most common composite outcomes that was reported being complete response which was usually defined as no vomiting as well as no use of rescue medication. And then we also included other miscellaneous outcomes that are listed there including quality of life. And then for harms we used…included the usual harms outcomes. Next slide.

So here is the details of our Medline search. We searched Medline from October 2008 through December 2009 for new controlled clinical trials and we found a total of 35 new citations. Next slide.

And among those 35 new citations we identified six new potentially relevant trials; five of which addressed gaps in previous evidence. So there were…among the head-to-head trials two evaluated patients that were undergoing highly emetogenic chemotherapy and two evaluated patients following surgery. In the trials…head-to-head trials of adults undergoing highly emetogenic chemotherapy both compared palonosetron to granisetron and they would be the first trials of this comparison as previously we only had three head-to-head of palonosetron all together and all of them only involved comparisons to either dolasetron or ondansetron. And then for post-operative nausea and vomiting only one of the

two new head-to-head trials addressed the gap and that is the trial of ondansetron…the orally disintegrating tablet form of ondansetron and that was simply because there were…previously there have been few pre trials…head-to-head trials involving a comparison to that particular formulation on ondansetron. And then as for the placebo-controlled trials there were two and both involved the comparison of aprepitant triple therapy to a control regimen of ondansetron plus dexamethasone and they addressed gaps in previous evidence as one would represent the first trial of aprepitant triple therapy is adolescents and the other would represent the first trial of aprepitant in 100% Chinese population. Next slide.

Provides the results of our searches of the FDA and Health Canada websites and here we didn't identify any new antiemetic drugs nor did we find any information on new indications or new safety alerts for the previously included drugs. So that concludes our summary of the findings from the scan and then here I'll note that based on the findings from the scan the DERP participating organizations voted against the full update of this review. So we have not fully evaluated those trials that I presented and the next time this review will be considered for a full update is estimated for December of this year. So I'll turn it back over to you for discussion.

Vyn Reese: Thank you, Kim. I'll take a motion to accept the scan.

Carol Cordy: This is Carol Cordy. I move to accept the scan.

Patti Varley: This is Patti Varley. I'll second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. The scan is accepted. Any questions from the committee? There are two stakeholders that wish to speak. The first is Peter Wack from Merck and the second is…on deck is Dr. Shelley Blam from Elsai Inc.

Peter Wack: Good morning. My name is Peter Wack. I'm a Senior Reimbursement Specialist for Merck's oncology division. I'm here to provide public comment on Amend and Amend for injection or aprepitant and fosaprepitant. And I just wanted to ask the P&T Committee to maintain Amend in its current position with no therapeutic interchange for the following reasons. Just to remind the committee that aprepitant and fosaprepitant and are a unique class of agent with no generic equivalent that is used in combination with other antiemetics to prevent chemotherapy induced nausea and vomiting in patients receiving highly and moderately metogenic chemotherapy. It targets the central pathway by blocking

the NK1 receptor and you use that in combination with the 5HT3 antagonist which blocks the peripheral pathway in the gut to provide additional protection in cancer patients receiving emetic chemotherapy.

The three drug combination that includes aprepitant, a 5HT3 and dexamethasone is recommended per the National Comprehensive Cancer Network in the prevention of chemotherapy induced nausea and vomiting in highly and moderately emetogenic chemotherapy regiments and I ask that, again, the committee continue to allow its utilization in cancer patients for those indications. And also I wanted to remind the committee that Amend is only promoted to oncologists and hematologists for the prevention of chemotherapy induced nausea and vomiting. So I know that there are other areas that antiemetics are utilized and I just wanted to make sure that all of you are aware that Amend is only promoted in the chemotherapy induced nausea and vomiting setting.

The final comment I'd like to make is to remind the committee that we have various configurations that Amendis available in. It's given for three days; the first dose given prior to the initiation of chemotherapy and there's a subsequent two oral doses given the following mornings on days two and three following chemotherapy. So providers have a couple of options on how they prescribe and utilize Amend. One being three days of oral Amend starting with 125 mg loading dose followed by two subsequent 80 mg capsules. And that is packaged in what we call a tri-fold pack. The second method they can administer Amendis by providing that loading dose as fosaprepitant or 115 mg of an intravenous dose at the time of chemotherapy along with their other IV antiemetics and then they would prescribe a bi-fold pack, which contains the two 80 mg capsules. The third is to allow both the unit use of the 125 mg loading dose capsules as well as the unit use of the 80 mg capsules to be available because in the hospital outpatient setting often times they will give the 125 mg loading dose in the outpatient setting and then provide two subsequent 80 mg to take home with the patient. Any questions for the committee?

Vyn Reese: Thank you. Questions? Our next speaker is Dr. Shelley Blam.

Shelley Blam: Good morning everyone. My name is Shelley Blam. I am a Cancer Biologist, patient advocate and currently serving as a Medical Science Liaison for Eisai. The American Cancer Society estimates that approximately 1.5 million new cases of cancer were diagnosed in the U.S. during 2009. Chemotherapy induced nausea and vomiting is a side effect of chemotherapy and can result in significant medical complications including hospitalization or ER visits. Untreated nausea and vomiting have the potential to cause dehydration, electrolyte imbalance, impaired quality of life, and among the most…are among the most feared side effects in patients receiving chemotherapy.

CINV is classified in two phases – acute and delayed. Acute occurs within the first 24 hours after chemotherapy administration and delayed occurs more than 24 hours after and may persist for up to five days. Aloxi is a 5HT3 receptor antagonist as you all know with a strong binding affinity for this receptor and little to not affinity for other receptors. Aloxi has a 40-hour half life, more than four times greater than any other agent in its class and 10 times greater than ondansetron. It is the only single dose IV 5HT3 receptor antagonist approved for the prevention of acute and delayed CINV in moderately emetogenic chemotherapy and acute CINV in highly emetogenic chemotherapy. Dosage for adults is a single 0.25 mg IV injection given approximately 30 minutes prior to the start of chemotherapy.

The efficacy and safety of Aloxi in mech was demonstrated in two phase three double blind trials involving 1,132 patients comparing single dose IV Aloxi with either single dose IV ondansetron or IV dolasetron. In these studies the primary end point was complete response rate defined as no emetic episodes and no use of rescue medication. In the first study Aloxi provided significantly higher response rates versus ondansetron in both the acute and delayed phases. In the second study Aloxi was demonstrated to be non inferior to dolasetron in the acute phase, but provided significantly higher response rates in the delayed phase that were statistically significant. The efficacy and safety of Aloxi in highly emetogenic chemotherapy was demonstrated in a phase three double blind trial involving 667 patients comparing single dose IV Aloxi with single IV ondansetron. Aloxi was demonstrated to be non-inferior to ondansetron in the acute phase. The most common adverse events include headache and constipation which are comparable to other agents in the class.

Jeff Graham: Please conclude your remarks.

Shelley Blam: And I'm finished. Thank you very much and I'll entertain any questions.

Vyn Reese: Thank you. Questions from the committee? Thank you. Any further discussion of this group?

Jason Iltz: This is Jason. I just wanted to sort of reiterate what the first stakeholder brought up and that was that aprepitant is part of…should be part of a three drug regiment for chemotherapy and radiation and I know that the Medicare sponsored drug programs have followed suit with that recommendation that's really a national guideline. Are our agencies also making sure that we have a 5HT3 onboard and dexamethasone before that medication is approved?

Donna Sullivan: This is Donna Sullivan. Are you talking about the Amend? At this point in time we don't have any prior authorization or any requirements for Amend. So I guess the answer is no.

Jeff Thompson: And this is Jeff Thompson, DSHS. Right now there is no connection between the two drugs in our prior authorization that I know about.

Charles Agte: This is Charles Agte. We do have criteria on Amend but I don't know off the top of my head what it is. But we do have some criteria. Because currently it's listed to say it's not…not on the PDL. It was excluded from the class. So not subject to TIP or DAW. So there has to be some sort of review process for those particular meds. And if there's not we really should look at those national guidelines and follow suit with what the other payers are doing in terms of making it part of that three-drug regimen for those specific patients.

Jeff Thompson: We can look at that. This is Jeff Thompson. We are just…just real quick we have had a number of requests from pediatric offices and other to make these drugs available for pediatric nausea as well and so we are in the process of…I've talked to Nicole in reviewing, you know, what our prior authorization and our EPAs will be for these drugs to make them more available and we'll take that under consideration for the three drug regimen.

Charles Agte: This is Charles Agte again. I can say that our criteria on…we do have criteria on Amend. It does require prior authorization. I know part of the criteria is that it be used in conjunction with other antiemetics. I just don't know off hand if that's specific to the 5HT3 or if we have…exactly what the…what the set of drugs that you have to be using it with are but we do have a requirement for it to be used in conjunction with something else.

Vyn Reese: So it is available currently for those patients and it's well established that's part of a three drug regimen for nausea and vomiting…for delayed problems. Any further discussion of this class? Let's look at the prior motion.

This is Dr. Reese. As I remember we left the aprepitant and fosaprepitant out of the class because of their unique properties and their ability to affect delayed nausea and vomiting and that they weren't really comparable to some of the shorter acting agents and that's why we left them…in their own separate niche. I think they're still being reviewed though as antiemetics. So even though they're not specifically in this class they're still being reviewed as antiemetics.

Carol Cordy: This is Carol Cordy. Pregnancy is not on there. Is that…is it left off…is that a mistake or is it not on there because of it not being approved or…the studies all included pregnancy as one of the inclusion criteria. Does anybody know?

Patti Varley: This is Patti Varley. So Carol are you asking if we can amend this to add into the list pregnancy?

Carol Cordy: I don't think all of these medications are used in pregnancy but certainly ondansetron is. So somehow that seems like it should be in there.

Barak Gaster: This is Barak Gaster. That's what the scan was and so we should add that as an indicator.

Vyn Reese: So we could modify the motion by saying chemotherapy, radiation therapy, pregnancy and post operatively. Is that what we're saying? We have studies for pregnancy that's for certain.

Barak Gaster: Right. This is Barak Gaster. I guess we haven't actually reviewed the evidence and so the question is whether that was an indication of the last update or not. Or is this a new inclusion criteria that is new to this scan today?

Jeff Graham: Kim, was…pregnancy was included in the last full update wasn't it?

Kim Peterson: Yes, it was. We've never found any trials for the use of these drugs for pregnancy. So there's a lack of evidence but it was included. We always look for it for studies on it. So in this scan we again did look for studies for using these drugs in pregnancy.

Patti Varley: This is Patti Varley. We may have deliberately left it off if there was no data on it even though it was in the review there was no data to support it so I think that would have been probably likely that we chose to leave it out because there wasn't evidence of safety, efficacy in that population because there was no data.

Carol Cordy: So Kim is that true for all of the previous studies, updates? There just isn't any pregnancy…

Kim Peterson: So for…so we've only updated this review once in the original review and in the first full update as well is in this scan. We've never found any controlled clinical trials for using these drugs to prevent or treat nausea and vomiting for pregnancy.

Vyn Reese: This is Dr. Reese. So it's an off label use essentially and it's not FDA approved?

Kim Peterson: That's correct.

Vyn Reese: Right. Okay. So we don't have to add it.

Carol Cordy: So just for my information is it though covered under something else for pregnancy?

Chuck Agte: Washington Medicaid does have criteria around its use for hyperemesis gravidarum, yes.

Vyn Reese: So let's look at the motion again. Looks like it's okay. I'll move that the…I'll make the motion as previously made on the April 15, 2009 meeting. This is Dr. Reese.

Barak Gaster: This is Barak Gaster. I second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. Okay. Next item on the agenda is the drug class review on the Macrolides. This is a preliminary scan.

Jeff Graham: Sujata, are you on the line?

Kim Peterson: Jeff, this is Kim. Are you ready for the macrolides?

Jeff Graham: Yes, we are.

Kim Peterson: Yeah. She's here and so I'll turn it over to her. And then as it turns out Susan Carson had a family emergency today. So I'm going to be presenting the PPIs and the Hormone Therapy one. So just a heads up to that. Do you think you'll take a break after Macrolides or do you think you'll continue right on to…

Vyn Reese: That's what's scheduled is a break after Macrolides and we'll look at the…

Kim Peterson: Okay. Well here's Sujata.

Vyn Reese: 10:45 we'll open up on the scan of the estrogens. We're ready. We have the Macrolides slides up when you're ready.

Sujata Thakurta: Hi. This is Sujata and I'll be presenting to you the preliminary update scan on Macrolides. So let's just go straight to slide #2.

So the original report was…originally report on Macrolides was prepared in August of 2006 and searches were conducted through first quarter 2006. This drug class was scanned once before in January 2009. So this is the second scan on Macrolides.

The next two slides list the inclusion criteria in populations, interventions, effectiveness and harms outcomes. So you can just look at them.

Slide 5 lists, you know, on slide 5 I have the FDA and Health Canada website search results and unfortunately we did search for drugs and…for new drugs indications and black box warnings for the included drugs but we were not able to find any.

Slide 6. For this scan we conducted…we searched Medline from October 2008 to May 2010 and were able to identify 144 citations.

Slide 7. There were actually only two potentially relevant trials that were obtained from the search this time. One of the trials on adolescents and adults with streptococcal pharyngitis/tonsillitis comparing extended release to immediate formulations of azithyromycin and the other is a trial on [inaudible] children with Otitis Media comparing azithyromycin to amoxicillin. There were 13 potentially relevant trials that were found from the previous scan. So all together there are 15 trials that have been identified as potentially includable since the original report was produced.

We also searched for systematic reviews produced by the Agency of Healthcare Research and Quality and the Canadian agency for drugs and technologies in health, but we were not able to identify any systematic reviews on macrolides that were published since the original report was completed. That concludes my presentation. Do you guys have any questions?

Vyn Reese: Thank you. This is Dr. Reese. I'll take a motion to accept the scan.

Sujata Thakurta: Excuse me.

Jason Iltz: This is Jason. So moved.

Vyn Reese: We're just accepting the scan. I'll take a second to that.

Duane Thurman: Excuse me. Is there any stakeholder input?

Vyn Reese: We're just accepting the scan.

Duane Thurman: Aw, sorry.

Christine Klingel: Christine Klingel, I'll second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. Questions from the committee? Stakeholder input? Anybody wish to speak on Macrolides? No stakeholder input. So any further discussion?

Jason Iltz: This is Jason. I just think this is probably one class where we can certainly archive it and put it on the shelf for a while. There's, you know, not a lot of changes happening with this particular medication class. All of them are available generically. And so if we're making those budgetary decisions this is probably one that can kind of fall to the bottom of the list.

Vyn Reese: This is Dr. Reese. I totally agree. This probably should be archived. I don't know whether…to the presenter. Do you know if it's archived or if it's going to be archived or not? Do you have any idea?

Jeff Graham: Vyn, this is Jeff Graham. This is a review that only Washington did. This is not a full DERP review.

Vyn Reese: Okay. I don't see the point of this. This is sort of a very dormant class and as it has already been mentioned the drugs are all generic. They've been out for quite a while and there's nothing happening here. So…

Duane Thurman: This is Duane Thurman. The history on this is that we went…several years ago the legislature thought we had done such a good job with 25 drug classes they said do 50. And we had to explain that not only would that, you know, that we split the cost so we are tied with what the other DERP participants do and we did a cost analysis to see at what point it would cost more to review the class than it would result in any kind of savings as a result and so we ended up with two drug classes that Washington did only and this is one of them. I think as we evolve the question comes as to what…what classes should remain on the preferred drug list but that gets to be very complicated because we don't want to suddenly take off the ones that cost us a lot of money. But I think that's an issue that we need to look as to whether, you know, I don't think this was a good fit from day one. But it was a result of a budget decision three or four years ago.

Vyn Reese: Right. But it seems dated at this point. This drug class…it's antibiotics. They're not drugs that are used long term. They're inexpensive and they're all generic. So it seems foolish to spend resources that are needed elsewhere in reviewing this class again unless something dramatic happens here. There may be some great drug in the pipeline that's coming out in this class that we're not aware of but until then I would move that we archive this.

Duane Thurman: Okay.

Barak Gaster: This is Barak Gaster. I move that we reiterate the motion from April 15, 2009.

Vyn Reese: Is there a second?

Deb Wiser: Deb Wiser. I second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. Good. Now we're scheduled to be adjourned until 10:45 and we're leaving a little bit early. Is that the schedule? It doesn't matter that much.

Jeff Graham: I think that would be fine to do because we will have plenty of time.

Vyn Reese: Right. Okay. We're now adjourned for a break until 10:45.

I believe it's Kim Peterson. Are you on the line?

Kim Peterson: Yes.

Vyn Reese: Okay. Great. The first slide is up and this is the drug class review on hormone therapy for post menopausal women or women in menopausal transition stage, a preliminary scan. Go ahead and begin.

Kim Peterson: Okay. So the…I'm going to be presenting results from our June 2010 preliminary update scan for this review. Let's go on to the next slide. So this slide lists the most recent activity on this review, which was the completion of a preliminary update scan in May of 2009 for consideration of update four of this review. Otherwise the last full update was completed for this review in October of 2007. Next slide.

The next few slides outline the inclusion criteria and as Vyn mentioned for populations we included women experiencing menopause whether that be natural or surgically induced as well as women transitioning through menopause. So women in the perimenopausal state. Next slide.

For interventions we included oral, transdermal and vaginal formulations of the seven hormone therapies listed on the slide. Next slide.

Here's our included outcomes. So for effectiveness we focused on the outcomes of hot flashes…related to hot flashes, other symptoms, quality of life as well as

prevention of osteoporosis. And then we did the usual harms outcomes. Next slide.

Now for a quick summary of the methods we used in this scan to identify new evidence. So to identify potentially relevant controlled clinical trials we searched Medline from May 2009 to May 2010 and we found a total of 180 new citations. And then here is the other review where we applied our new methods to identify new comparative effectiveness reviews that have been completed since our last update and searched the websites of the Agency for Healthcare Research and Quality and Canadian Agency for Drugs and Technologies in Health—more reviews completed by those agencies. Next slide.

So here's the results of our literature searches. We didn't find any new comparative effectiveness reviews but we did find 11 new potentially relevant trials; all of which were placebo-controlled and evaluated six different products based on various effectiveness and efficacy outcomes as listed here including hot flashes, vulvovaginal symptoms, sexual function, cognition, CHD, and quality of life. So no new head-to-head trial at this time only placebo controlled trials. Next slide.

Here's the results of our FDA and Health Canada searches. For new hormone therapies and information on new indications and new safety alerts for previously included drugs. We didn't identify any new hormone therapy products or any new safety alerts for previously included products but we did identify a new indication for the 10 mcg dosage regimen of estradiol vaginal tablets. That being treatment of atrophic vaginitis due to menopause. That's the last slide.

So I will also note that based on this evidence, those 11 placebo-controlled trials, the DERP participating organizations voted against a full update in June and so we haven't fully evaluated those trials, those placebo-controlled trials and the next time this review will be considered to be rescanned won't be until June of next year. So I'll turn it back over to you for discussion.

Vyn Reese: Thank you. Is there a motion from the committee to accept the scan?

Susan Rowe: So moved.

Vyn Reese: Is there a second?

Carol Cordy: I second. Carol Cordy.

Vyn Reese: Susan Rowe was the one who made the motion. Okay. All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. Okay. The scan is accepted. Are there any questions from the committee? Any stakeholder comment on this drug class? No one signed up. So let's look at the prior motion. Was somebody going to make the motion? It's a long motion. It's in here…it's in our folder.

Woman: Would it be possible to move the screen down to read the rest of the screen?

Carol Cordy: Thank you.

Vyn Reese: Do we have a motion?

Patti Varley: This is Patti Varley. I move that we accept the motion from June 17, 2009.

Vyn Reese: Is there a second to that motion?

Deb Wiser: This is Deb Wiser. I second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. Okay. Thank you. The next item on the agenda is the scan on proton pump inhibitors. Just a second. We need to get the slide up. Now we have the slide up.

Kim Peterson: Okay. So these are going to be the results from the preliminary update scan of this drug class that we performed back in March of 2010 for consideration of the sixth update of this review. Next slide.

This slide lists the most recent activity on the review which was the completion of the fifth full update in May of 2009. So pretty recent. Next slide.

The next few slides outline the inclusion criteria. So for populations we included both adults and children with symptoms of gastroesophageal reflux, peptic ulcer or NSAID-induced ulcer. And for interventions we included the six products listed on this slide. Next slide.

Here's the included outcomes and for effectiveness we included outcomes related to symptom improvement, endoscopic healing, eradication rates, functional outcomes and quality of life. And we included our usual harms outcomes. Next slide.

So here's the details of searches of the FDA and Health Canada websites for…to identify new proton pump inhibitors as well as information on new indications and new safety alerts for previously included drugs. And we did identify a new proton pump inhibitor. That being dexlansoprazole which was approved by the FDA in January of 2009. And then for the previously included drugs we didn't identify any new indications but we did identify a new safety alert for omeprazole. So in November of 2009 the FDA notified healthcare professionals of new safety information concerning an interaction between the anti-platelet drug clopidogrel and omeprazole that we think was based on new observational data showing that when clopidogrel and omeprazole are taking together the effectiveness of clopidogrel is reduced or can be reduced and that separating the dose of clopidogrel and omeprazole in time isn't enough to reduce this drug interaction. So I'll note here that we…so we've heard that there was a recent observational study in we think the New England Journal of Medicine about this. But in the scan since we only searched for trials the scan didn't pick this up. So we didn't find any trials related to…that provided evidence regarding this drug interaction. Next slide.

And then here we just noted that a similar advisory was issued by Health Canada in August of 2009. Again, to inform the public about the potential interaction in this case they are relating it to all PPIs and clopidogrel as I described that the concern being that taking them together could lead to a reduction in therapeutic response of clopidogrel. Next slide.

Vyn Reese: Could we stop…can we ask a couple of questions. Excuse me. Pardon me. Can we ask a question right here?

Kim Peterson: Oh sure.

Vyn Reese: Actually as I understand there's been new data suggesting that this interaction may not be that important.

Kim Peterson: Oh is that right?

Vyn Reese: Yes. And there's also a problem in that, you know, the patients who have H2 blockers substituted for PPIs have higher risk of a GI bleeds. So it's a concern. I mean, you know, I know this is the official warning right now, but this is an area of confusion I think. This is Dr. Reese.

Kim Peterson: Sounds like it's…so it's been evolving since we have done the scan even. So, yes, we didn't…I don't know what kind of evidence that you're referring to.

Vyn Reese: It's more observational studies. It's not…

Kim Peterson: Probably observational again I would guess. So that will be something that we'll be wanting to look for in the next scan of this review. I'm kind of jumping ahead of myself here, but the drug effectiveness review project participating organizations voted against updating…a full update of this review at this point. So, you know, we won't be looking at conducting another scan for…until a year from now or I guess a year from March. Do you have other discussion on that before I go on?

Alvin Goo: Yeah. This is Alvin. Actually since that FDA in 2009 there have been a few observational trials and one randomized trial, the COJENT(?) study by [inaudible] that could suggest that the…although there is a drug interaction clinically that that drug interaction might not be clinically relevant and that there does seem to appear that there's an increased risk of GI bleeds in patients without the PPIs.

Kim Peterson: I see.

Alvin Goo: So I would just recommend that if you're not going to be looking at this class for another year or so that the committee here find or review this new data through some group to just make sure that this indeed is clinically relevant and that we're not…currently their policy is that this is inhibited the ability to prescribe PPIs to patients with clopidogrel based on this FDA warning and that that in fact might lead to some higher rate of GI bleeds that I think we should re-assess this drug interaction. You can go ahead.

Vyn Reese: Yeah. Go ahead with your review. This is data that was presented since…presented since this was last looked at. So it's not…we can't really make it part of this discussion but it has quite a bit of importance in how we prescribe these drugs.

Kim Peterson: Uh huh. It's amazing how quickly the landscape is changing on this. Okay. So now the…slide 7 provides results of our searches for our new controlled clinical trials and we searched Medline from November 2008 through the fourth week of March of 2010. Sorry, we left off the month on the slide. So…in that search we found a total of 180 new citations. So quite a few relative to some of the other classes we've discussed today. Next slide.

So among those 180 [tape cuts out] trials met our inclusion criteria based on our abstract and title review. And four of those were head-to-head trials. Though none included the comparison of the new PPI dexlansoprazole as directly compared to any other PPIs. So the new head-to-head trials all involved the comparison of esomeprazole to other PPIs. Next slide.

So the remainder of the studies outlined in the last few slides were primarily placebo controlled. Three involved either lansoprazole or omeprazole for maintenance treatment and then there were two others that were conducted in children and adolescents. And this is an area for which we'd previously only ever found one placebo controlled trial I think of omeprazole in infants with GERD which found no significant difference between omeprazole and placebo in controlling symptoms or acid exposure times. So a bit more evidence in children and adolescents was found in this scan. Next slide.

And here's the last slide and it outlines the details of the remaining trials that we found in the scan. One was comparing step-up versus step-down treatment with antacids, H2 antagonists or PPIs, which I think is a new key question we added for the last update looking at different dosing strategies and then the other two evaluated the effects of the new PPI dexlansoprazole in patients with GERD. One being a short-term and then the other evaluating its use as maintenance treatment. So there was a new drug but we only found a couple placebo-controlled trials for it at the time of the scan in March. So let's go on to the last slide and then I'll just say again that as I mentioned before although there's a new drug and some new placebo-controlled evidence as well as that safety public notification of the potential interaction between PPIs and clopidogrel the DERP participating organizations elected or voted against full update of this review as of March. So usually it's another year before we're going to look at whether or not we want to re-scan this review for consideration of a full update. So probably about March of next year is when we'll be looking at this review again. So I'll turn it back over to you for discussion.

Vyn Reese: Okay. Thank you. I'll accept the motion from the committee to accept the scan.

Deb Wiser: This is Deb Wiser. I move to accept the scan.

Vyn Reese: And a second?

Barak Gaster: Barak Gaster. I move to second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. This scan's accepted. Any questions from the committee? Any other questions regarding this drug class? Is there any stakeholder input? There's no stakeholder input. We'll have to be aware that there may be other advisories regarding this class coming out. It's an area where there is quite a bit of discussion and further trials may further decide this issue about drug interactions with this clopidogrel.

Patti Varley: This is Patti Varley and I don't use this medication very much and in looking at this I am just trying to clarify something in my own mind. In reviewing the PPIs themselves this doesn't change necessarily the information about comparison within the group of PPIs.

Vyn Reese: No.

Patti Varley: What the information is saying is that there's new information regarding drug/drug interaction which is to me in my mind a separate issue than the issue of comparison within the group. Am I correct in that?

Vyn Reese: Right. But it's a safety issue though in this drug class though and it may be different within different members of the class. In other words some drugs…

Patti Varley: We don't have that information though.

Vyn Reese: …in this class may interact and other drugs may not. So it's deciding which drug to use. If that actually turns out to be true, which it may not be, there may be certain drugs in this class that would be preferred if clopidogrel was being prescribed. So that's the only big question.

Patti Varley: Right. And the way I read the information from the 2009 thing was that it was initially seen with one particular PPI but then there was at least…then there was at least some assumption indication that other PPIs could have equally…equal problems in the combination as well. So I think it's data we don't have yet but it sort of was that jump that sometimes we make, which is from an individual drug to a class effect and yet we don't have that data. Is that correct?

Vyn Reese: Right. And there's questions whether that data is even real.

Patti Varley: Right.

Vyn Reese: It's a lot of confusion in this drug class currently about that particular drug interaction. Any other discussion?

Jason Iltz: This is Jason. I just have a comment that's more of a housekeeping issue. I know we don't typically use brand names here, but one of the medications in this…it's actually not part of the PDL but it's listed in there, the dexlansoprazole recently went through a name change. So just to make sure that we update our list it is no longer called Kapidex. It is now called Dexilant, D-E-X-I-L-A-N-T I believe. So we'll just want to update that. There was some confusion with the name and it was getting…there was some errors in dispensing due to that.

Vyn Reese: And it wasn't…it actually hasn't been reviewed in a complete…

Jason Iltz: Right. But it's listed here as…in our list.

Vyn Reese: We haven't seen the complete data on that drug yet.

Jason Iltz: And then another comment I just wanted to applaud the efforts of the agencies too because I know that this particular class in general has really had a hard look at it in terms of whether or not prolonged therapy is really appropriate in a lot of cases. So know that that's caused a lot of work for folks where, you know, after a certain period of time they're asked to go back and say, "Hey, is this really the best therapy?" And I just want to applaud those efforts to the agencies that are doing that work.

Vyn Reese: Any further discussion? Okay. It's been made…the motion has been made and seconded to…on the prior motion…to approve the prior motion. All those in favor say, "Aye."

Jeff Graham: You haven't made that motion yet.

Vyn Reese: We haven't made the motion?

Group: No.

Vyn Reese: Okay. I'm looking up there and I'm being mislead apparently.

Deb Wiser: This is Deb Wiser. I move to…

Vyn Reese: I apologize. That's my mistake. Let's go ahead and ask for the motion. I'll ask for the motion for…to approve the prior motion.

Deb Wiser: This is Deb Wiser. I move to reiterate the prior motion.

Vyn Reese: And a second of that?

Jason Iltz: This is Jason. I'll second.

Vyn Reese: Okay. All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. That's approved. Now we're adjourned for lunch. We'll reconvene at 1:00.

Let's all take our seats now and quiet down and we'll start the DUR meeting. This is Dr. Reese and I want to call the Washington State Drug Utilization Review Committee to order. The initial item on the agenda is looking at the minutes from the April 21st meeting. I'd like you to take a minute to look at those if you haven't already done that.

I'd like to put some corrections on my statements during those minutes. On pages 10 and 11 I refer to Dr. Farmer as Dr. Carson. So I want to make certain that Dr. Farmer is put in place of Carson. On page 24 it should be with a psychosis, not as a psychosis. Also on page 44 it's an internist and geriatrician. Again, that was sort of blurred together. Those are all under my comments. Any other additions or corrections?

Christine Klingel: This is Christine Klingel. On page 22 I think we were talking about Obra 90, O-B-R-A instead of over, O-V-E-R at the top of the page.

Chuck Agte: Dr. Reese, can you repeat your last correction you mentioned?

Vyn Reese: Okay. It's page 44 and it says I'm an internist and geriatrician. It states instead that internist in geriatrician. That's the third line of my little piece of that page. It should be and instead of in. Any other additions or corrections? If not I'll take a motion to approve the minutes as amended.

Woman: So moved.

Vyn Reese: Is there a second?

Barak Gaster: This is Barak Gaster. I second.

Vyn Reese: All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. The minutes are improved. The initial item on the agenda today is Dr. Jeff Thompson. He's going to be talking about abusive stimulant drugs used in treatment of ADHD.

Jeff Thompson: So this is Jeff Thompson. Just to sort of bring us back to where we…we had a couple of representatives here at the last meeting, Representative Hobbs and Representative Hurst. Representative Hurst is here to…because he's very concerned about some of the diversion as it relates to the stimulants. So for this DUR working with Chuck and Amy we brought some experts from DBHR. David Albert will talk to you a little bit about what they're seeing both from a…the survey work that DBHR does, the Division of Drug and Alcohol as well

as what they're seeing in the treatment centers and what's going on with some of the…some of the diversion issues within the colleges. And then I'll talk really very briefly about some of the things that were…tools that are out there. I'd really like to hear from you about how we can better educate the primary care docs because they touch the clients probably more frequently hopefully than police officers. And then Dr. Robert Hilt will be here to talk to you about the PAL program and the Second Opinion program and the red flags and stops that we've put in not only for the antipsychotics but also for the stimulants. And if you'll remember the provider access line is the five-day a week, eight-hour per day where you can get a consultation with a pediatric and adolescent psychiatrist. And so he's actively getting what, about 300 or 400 consultants a month?

Man: We have about 400 providers we consulted.

Jeff Thompson: So roughly around 400 providers and several hundred consults a month as it relates to the mental health drugs primarily the stimulants but now getting into the antidepressants and the antipsychotics. And so Bob will talk to you about what he's seen on the streets. With that maybe I'll first have Mr. Albert talk about what he's seen from the Department of Behavioral and Rehab and Mental Health.

David Albert: All right. This is David Albert. I'm the Senior Planner and Policy Analyst for the Division of Behavioral Health and Recovery. Um, I think we have some slides that we'll…

Leta Evaskus: I'm controlling them so you can just say next slide.

David Albert: Okay. So there aren't that many. So you can put up the first one. So first of all I have to tell you that the numbers around the abuse specifically of psychostimulants is um…the data are not there for the most part. They are not in good shape. Often the data are combined. Generally with all stimulants which can include amphetamines whether they are meant as psychostimulants or not. This is survey data from the National Survey on Drug Use and Health and it shows past month non-medical use of psychotherapeutics. You'll notice the stimulants category is highest in the 18 to 25, which is no surprise. Those are college age students. Second highest in the earlier age group. When we see abuse of psychostimulants generally speaking we're talking about young people. Next slide.

Here we see information, again, on lifetime non-medical use of psychotherapeutics. We see a relatively high percentage in the use of amphetamines which is split into two classes. I'll talk about national…the Washington state data in a minute. You'll notice on the second chart on the annual non-medical use of prescriptions Ritalin makes up roughly half of what

we see in the amphetamine category. It's interesting. A lot of the national surveys, including the survey in Washington State mind you, the Healthy Youth survey, used to only ask about Ritalin. And so we know that in fact, you know, basically we really want to get a good benchmark. We essentially need to double…double the numbers that we see when we ask for Ritalin. The new 2010 Healthy Youth survey being conducted this year does ask about the entire class of psychostimulants for use among 8th, 10th and 12th graders. Next slide please.

Oops. Oh, you took the other ones out.

Jeff Thompson: Why don't you talk about…I apologize there are a couple of slides that got added and then subtracted.

David Albert: That's fine. That's fine. In 2008 the Healthy Youth survey showed that roughly 5% of 10th and 12th graders had reported using Ritalin illicitly in the past 30 days. Again, since that did not include Concerta, Adderall, other drugs in the general category it's likely you could double that. But college surveys nationally are all over the map and not too many of them are very recent. The median seems to be around 8% of the student bodies at the colleges and universities have used these drugs illicitly in the past 30 days. But the range is quite high from a low of 4% up in this college surveys up to as high as 25%. So the range is quite large in that.

Now one of the other things that we are seeing again in the survey data among college students is that two or three years ago if you asked why you used it illicitly most folks will tell you that it was a study aid, at least a majority would have said it was a study aid. While there's a significant percentage that still says that the plurality is now for recreation. That we have actually seen a change in why folks are misusing these drugs.

Our treatment system is not seeing people entering…really very, very few entering where the primary substance of abuse is one of the psychostimulants. But that would seem to sound like good news except we have found…first of all looking at the 8th grade, 10th and 12th grade students there is a strong association between use of Ritalin without a prescription and use of prescription pain killers, opiates, to get high. We found for example among 8th graders 55% of those students who had used Ritalin without a prescription in the past 30 days had also abused a prescription opiate. It rises to 74% among 10th graders, 70% among 12th graders whereas the percentage…

Patti Varley: Can we ask questions during this?

Jeff Thompson: She's always first.

David Albert: That's fine.

Patti Varley: Ladies first. It's documented in the notes for you, Jeff. This is Patti Varley. I want to get back to a point you made just because I don't know if there is differentiation or if it was asked that way. But you mentioned for study aid and for abuse…

David Albert: Uh huh, recreation.

Patti Varley: Right. Did you ask about performance enhancing before to me that's a different category than just a study aid—staying up all night to study, but there is some documentation I've been reading recently of certain colleges that actually use it as a performance enhancer, which is different than a study aid.

David Albert: Yeah. Um, again, we didn't do the study…any of the studies or surveys. I'm just looking at the national studies. From the ones I remember I seem to remember them asking about study use…use it to help you study.

Patti Varley: To stay awake.

David Albert: I don't remember anyone asking specifically about performance aids.

Patti Varley: Okay.

David Albert: That's a good question. Um, so we are seeing this strong association between…at an early age starting in 8th grade between the misuse of psychostimulants and the misuse of prescription opiates. That's of grave concern to us because that's what we are seeing in our treatment system. At 12th grade, 12% of our students had misused…illicitly used a prescription opiate in the past 30 days and of that 12% more than half of them had used them three or more times. The numbers we are seeing among 18 to 24 year olds entering our treatment system for addiction to opiates is shocking. I mean it has multiplied by three in the past four years. And that's not even counting those who are receiving treatment for opiate addiction through suboxone in the private insurance system where there are now 13,000 slots. And the DEA anecdotally reports of the doctors who have a license to practice with 100 folks receiving suboxone the DEO reports they are all full. So we are seeing a massive problem and increasing problem around addiction to prescription opiates. And what's worrisome, again, is the link we're finding as early as 8th grade with the use of prescription psychostimulants and the abuse of prescription opiates.

Again, we don't really know why but it seems like the kids seem to say a drug that comes out of a bottle, is a drug that comes out of a bottle, is a drug that

comes out of a bottle. They may not be making those distinctions as clearly as it would be. They're getting in trouble because of it.

I guess that's what I have to say. Again, it's primarily a problem of the young. We don't see a lot of psychostimulant abuse among those over age 29 from what we can tell from the few questions we've asked. There are colleges that have programs now to try to deal with this; WSU in particular has a program that is specifically aimed at targeting the abuse of psychostimulants. There are some colleges that…I know Stanford has done this where their medical center will no longer do the prescribing of or fill a prescription for psychostimulants. You'll have to go to the outside to do that and there is some evidence at a few colleges around the country where indeed that has an impact on the illicit use of the psychostimulants. That's really all I've got.

Carol Cordy: I have a question. Carol Cordy. Has there been follow up? What happens to these kids when they turn 25 or 26?

David Albert: Well again we…yeah, got it. Well, again we do see the increase in abuse and dependence upon prescription opiates is across the board. For the first time now we are seeing…we have never seen this, we'd seen it in other states, but for the first time now in Washington State we have evidence of a cross over between the abuse of prescription opiates and heroin. We are now seeing 39…the last study I saw from the Seattle Needle Exchange showed that 39% of the people at the Needle Exchange claim to have been addicted to opiates before they had ever used heroin. If we look back four years ago it's like 4 or 5%. Again, this is new. We had not seen that until about two years ago. We are seeing it now.

Jeff Thompson: So let me just talk about some of the control points that are happening and I think some opportunities that we have and I think it's dialogue with you. You know, there really are, at least in the medical side, three control points—the physician who prescribes, the pharmacist that dispenses and then the clients who take the medications. On the physician side, you know, I think we still got a lot of work to do on trying to educate physicians, not you guys, but some out there about, you know, how do you screen, how do you intervene, how do you refer? Because at least…correct me if I'm wrong, David, I think only about 5 or a lot less than 10% of the referrals to drug and alcohol come from MDs.

David Albert: Oh for sure.

Jeff Thompson: Yeah. It's almost miniscule. So I think just like with smoking, you know, where it become sort of the fifth vital sign, you know, this has probably got to be our sixth vital sign and how do you actually screen? And so that's one of the things about looking at it. So a couple of things that are happening. One is we were just at, Jaymie and I were just at the meeting yesterday. So there is actually

administrative code moving forward to actually set standards for opiates that will be in the licensure boards to set standards around thresholds and red flags and what is adequate screening, what is adequate assessment, what is actually a red flag where you would refer to a substance and alcohol abuse either professional or a pain management specialist. And so within that and the agency medical director's guidelines, you know, we have a number of standard tools now for screening and assessment that will be easily sort of turned over before looking at whether it's alcohol or stimulants or drugs of abuse or prescription drugs. And so those are easily transferable and within the next year they will actually become hopefully standards of care built into the licensures for pharmacists, nurses and MDs. So that offers us I think a real leg up to say, "Here's the tools. Here's the standards and now how can we roll those out?"

Along with that is the AMDG guidelines I think is the opportunity, you know, to start setting up what are the thresholds and, you know, at the pharmacy, you know, what is refilled too soon? Or what is a cash trade? Or as David said maybe the venues of service are something that we need to look at because it's more than stimulants, it's also the opiate issues. And if you look at…if you remember some of the data that we brought we're seeing actually opiate related deaths now down into the teenage years, which is actually quite concerning and if you look at the 2006 data we're number seven now in prescription related narcotic deaths in the nation and growing. And so that's why there's a lot of activity.

I think…the other part is I know many of the pharmacists have got their little sort of notepads about abuse and misuse. I'm hopeful that in the next five years with the health information technology and EMR that we'll have actually a prescription monitoring program for all drugs. That will come eventually so you'll be able to see who's prescribing what to who, where, when, and so stay tuned. As you know you can always get a prescription history from Medicaid. It's a little bit…as Barak has counseled us many times that it's a little bit cumbersome. It's the best we got right now. But all you have to do is, you know, send us those informed consents and we'll fax you back a prescription history for what we know about.

Patti Varley: And this is Patti Varley. Beyond when that is the case in regard to my understand is right now if I have a patient and they're using multiple pharmacies to fill…so they use Walgreens in one week and then they use Rite-Aid the next I can go to Walgreen and get their fill history on my patient but that won't necessarily tell me what got filled for that patient at Rite-Aid. And so that's a problem. I do want to say though on a very positive note a recent situation where a pharmacy did refuse to early fill a prescription of a patient of mine, which did lead me to identify abuse of that patient. So when it works it's very helpful to those of us who don't know that's occurring.

Jeff Thompson: And I have to say when you end up in a crisis like this I think measures like red flags are really important. So, you know, as I've said, you know, do we have a red flag where there's a cash stop at the pharmacy. You know, no more than a couple three hundred dollars to pay for a stimulant or an opiate. But that requires everybody to come to an agreement and that's why you can even see some emergency rooms actually saying, "You only get three prescription related narcotics for non-cancer pain in a year in our ER. Thank you very much." Now I think a prescription monitoring program will, I think, help. They're not real time, you know, there's usually a delay of a week or two. So you can have shoppers but I think, you know, one of the solutions is to have a prescription monitoring program as soon as possible for all drugs. Because in addition to people not, you know, taking too much stimulants and narcotics, our diabetics and asthmatics aren't taking their medication either and that's a whole other issue. Next slide.

So I think, you know, in the treatment things that are going on, you know, we do pay for a lot of treatment. What's our budget now in the agency formerly known as DASA? So DBHR. It's close to $200 million.

Man: It's about $170 million a year.

Jeff Thompson: $170 million that we pay. This is not for Medicaid only. This is for all people that meet the financial requirements that can get drug and alcohol treatment and David and his group, along with David Dickerson they pay for that across the state. I've found that most physicians and pharmacists really don't even know how to make sort of avenues into those and so we've been actually working on those communications. But if it's not part of that sort of sixth vital sign, you know, where now I know how to pick up a pad and write for a smoking sensation. It's not on the thought process so we've got some areas there.

We actually do now have tapering plans that are in the agency medical director's guidelines. We could easily adopt tapering plans for people that are addicted to stimulants. We do have detox and we have recommendations for urine and drug tox screenings. One of the things we're also doing nationally is we're asking for new mental health codes so that we can actually not just code and be paid or psychotherapy, but we're asking for codes for behavioral modification, cognitive therapy, MST, PPP, a whole bunch of codes and we'll see how that goes.

So Carol, hopefully in 2012 we'll actually have codes for actually mental health therapies which could be actually related to substance abuse that we will pay for and we'll see if we translate that to primary care versus mental health. It will be an interesting conversation. And then there's a lot of a recovery and support groups. So I'd be interested in talking with you about how do we get the

message? Does every doc know how to refer to Alcoholics Anonymous, Narcotics Anonymous, you know, how to get a refer in for a drug and alcohol screen at one of the DASA related treatment facilities? That has actually been a struggle. For example, I've been doing county community meetings where I've asked mental health…the substance abuse professionals and the medical professionals to sit at the table and in some counties that's the first time they've sat at the table together in their history. So that tells you it's not something that can be solved from Olympia. It really is creating the relationships in the community that I think is very important. Next slide.

I think the drug companies actually, you know, have some very good resources out there. From Shire there is actually a number of tools that you can on Medscape and you can get actually CME. This one is specifically talking about abuse and misuse from this particular class. It didn't take me very long to find these. I think what we can do is start making these available and it's a freebie. It's a question of taking the time. And is it relative to my practice? Next slide.

And then I think from Abbott I actually found this tool to be really very effective and I think we'll talk with David Dickerson and David Albert about whether this might be a tool that we want to get out there to assist not only the monitoring at the family level, but the security at the provider level and some things around disposal and that's been a big huge effort with Department of Health. How do you dispose of and this gets to the issue of what's in the medicine cabinet? How do you secure it? And so it's a nice check off. It's free and so if you have edits to this I mean this could be a tool and we'll talk to Abbott about using this in some communication. Next slide.

So the one thing I just want to leave you with is that if you remember I think you came up with some very good guidelines so when we are looking at the generics first with Adderall XR, instead of XL, sorry about that. I keep doing that. Um, it's a tick problem. There's medications for that isn't there? All right. So in any case, you know, what we do is we've said that we definitely do not want to force the prescriptions of generic Adderall out there and so if there is a history of substance abuse in the family or the individual being prescribing to we are fine with a prescription for Strattera or perhaps the patch or some other alternatives out there and all they have to do is indicate that in the prior authorization. So Generics First is not about, you know, sort of pushing more methylphenidate or dextroamphetamine and then Bob will now talk to you a little bit about what we're doing with the education around the provider access line, what he's seeing out there as he touches those in consultation and then some of the red flags we put out there on too much, too many, too young, and we actually have now red flags in the state where at least in Medicaid you can't prescribe at large dosages unless you talk to Bob.

I have to give the same lecture…or not lecture, talk to King County so I have to leave. So Chuck and Amy are here. They will take your direction. But if there's opportunities for us for education, and I would encourage you to look at the new agency medical director's guidelines because whether it's stimulants or opiates I think we have pretty much all the tools. I think the difficulty is how do we educate and agree on consistency of use of those tools? Any questions from mine?

Vyn Reese: Thanks Jeff.

Jeff Thompson: All right. Thank you.

Vyn Reese: So Bob we'll turn it over to you then.

Bob Hilt: Hi. Is this working? Now it is. Excellent. So I'm Bob Hilt. I'm a Child Psychiatrist and Pediatrician. I work at the University of Washington and Seattle Children's and I work with a couple of different roles for the state. One is I'm one of the consultants for the mandatory second opinion program and I also run the partnership access line which is that elective consultation program for primary care providers.

When I prepared these slides I had the idea that the P&T Committee was most interested in getting community provider feedback about these programs. I wasn't preparing these slides with the idea towards, "Oh we're going to talk about illicit use of substances." So I'll just kind of run through this really quick to tell you about the programs and that the topic of the day is really about illicit use of substances. These are less applicable. So next slide.

What the PAL program is is essentially a toll free number where a primary care provider picks up the phone, calls us and talks to the assistant who says, "Okay, who's calling? Who are you calling about? We'll get the doc on the line with you," and then connect to me or one of my colleagues. We also have social workers that work with the program who provide assistance with connecting to community resources such as I'm having problems finding a therapist for this family or the like. We also provide outreach lectures and we've done 22 different educational conferences around the state to try to educate the community. Next slide.

When we talk on the phone very often times that answers whatever the question was that the primary care provider had. We have the ability and its inherent to the program that if we cannot answer the question adequately over the phone that we'll do a full consult and we use TeleMedicine for that because…next slide.

This is the region that we're supposed to be operating in. The shaded areas are the PAL regions. The program's officially taking place. It isn't the entire state because of the budget. We're certainly not able to ask for things to increase in the last budget cycle. The little stars are telemedicine sites and the one on the bottom is in the wrong spot. It's actually the Tri-Cities. Next slide.

The community feedback about the PAL program. We did a pre- and post-implementation survey serving the primary care community and not surprisingly we asked primary care docs before we implemented what kind of…what is it like trying to get care for your patients. Of the 253 docs who filled out surveys only one in five thought they could access a child psychiatrist for a Medicaid client when one was truly necessary. 30% thought they could find a therapist for a child for a Medicaid client when one was truly necessary and only 23% said that they…responding to this exact line with existing resources I can usually meet the needs of children with psychiatric problems. So not a big surprise to us but it kind of confirmed that the…what things were like out there. Next slide.

When asked what the biggest challenge was in providing mental health services for children they said access by enlarge relative to everything else. Next slide.

These are some of the feedback questions and again I know I'm going through this quickly so that I can address the other topic questions today. When we do these telephone consults we, on the first time and the fifth time and every fifth thereafter, send them a little survey saying, "Hey by the way how was that for you? Did it meet your needs?" And these are some of the questions we asked of them and it's actually rather boring. They said everything is good about it. Go on to the next slide.

They're extremely satisfied with the access. They don't think it's difficult to use. They think it really helps the care of the children. It even fits breaking out in the middle of a busy practice day it even fits to call and my experience with getting these docs on the phone and I have been one of those docs myself at one point, it's hard to get them off the phone. They just really want to talk and "Oh by the way I saw this other thing and what do you think about that?" They're very positive interactions. Next slide.

Those who called us multiple times were even more satisfied even though those numbers were all very high and importantly starting to change the knowledge base. Primary care providers said they're more confident about managing psychiatric problems after doing PAL consultants after that. If those who receive five or more PAL consults noted that they had significant improvement in their ability to find resources for patients, more confident in treating psychiatric disorders and more confident in being able to treat ADHD and the internalizing disorders which is depression and anxiety. Next slide.

Then the other thing that we've been doing is second opinion medication reviews and these are the mandatory reviews the panel is always probably aware of. Next slide.

The first set of categories for mandatory reviews is the ADHD guidelines and they've been in place since 2006. So there's a mandatory review for ADHD prescription for someone less than age 5. High dose methylphenidate greater than 120 a day or dextroamphetamine greater than 60. Strattera high dose or a combination of two meds. Sorry, combination of medications from two or more categories such as an amphetamine plus say methylphenidate plus dextroamphetamine or Strattera plus dextroamphetamine, etc. Next slide.

We did do a community survey back in '08 and '09 and not everybody returned the surveys asking how it was done. Go onto the next slide for results.

People thought the purpose of the review was clear and if not we clarified it. They thought the scheduling of review was timely and convenient. Now we at Seattle Children's we weren't the only site starting to do these reviews. We became the only site as time went on due to scheduling difficulties and consistency between reviewers. We have, as an operating standard that we offer a telephone discussion with every time that this has been flagged for review. Frankly that's because people's written records are often poor and do not adequately justify why someone needs the medicine. So we try to give people every change they can. But they can tell us, "No, no, we'd rather just do it on records only," and we do it based on that. People are kind of split. This is on the bottom of whether they thought the review was useful or not. Maybe half or so thought it was useful. Those who were finding it not useful, I can say as a reviewer, and we didn't ask in this survey, these were more likely to be the specialists, the psychiatrists getting reviewed and they just said, "Aw, this is just a hassle." Next slide.

Again, with the ADHD reviews asking them general questions. Did they think it's important for second opinion reviews to be happening at all. Most people said they thought, "Yeah, it's generally a good idea. Just not for me." And they thought it was important to do things to improve variance and prescribing patterns. So again in the general sense. Next slide.

The other feedback that we got…all the written feedback we got was that generally people said…some people said it was nice to have a second set of eyes and opinions, some people said it was just unnecessary and kind of a hassle to do this. Go on to the next slide.

Then antipsychotic reviews came along. These are the guidelines that have been agreed to over a year ago and the…we've been doing reviews based on this for about a year now. As you can see it's a much more complicated table. With ADHD reviews we did not divide things out by age so that technically a 6-year-old could get 120 mg of Ritalin and it doesn't get flagged for review. In this system it's divided up by age and dose. Next slide.

Before we implemented it we surveyed the mental health specialist community and surveys were sent to the psychiatrists and psychiatric nurse practitioners in the state and we only had 33 people respond. Next slide.

And they said basically we generally agree with the thresholds and that it's probably a good idea to review medications – antipsychotics given to kids less than 5, just not me. And then the next slide.

The hassle factor is really the big downside. These reviews, these mandatory reviews are only happening and those of you who are providers in the room know after a denial occurs at the pharmacy. So the family is experiencing, "No you can't get this medicine," and in fact if the provider's office isn't very quick about responding to the notice from DSHS it's possible for the family to get a letter saying, "Your doctor didn't respond and therefore you're not getting the medicine." The system can mean the child is without stimulant for a period of time. If they are new to Medicaid and they've been on it for a while but now it's hitting a red flag, we're less concerned about that with stimulants than we were with the antipsychotics. And so we created this child in crisis standard, which many of you know about. If the family goes to the pharmacy and says, "But I gotta get it now. My kid's in crisis." They can get 60 days worth. If the prescriber writes it on the script "child's in crisis" they can get 60 days worth while all this review stuff is pending. Part of the reason for the denial as I had it explained to me there is no record to get authorized until a denial occurs. There isn't a way to do this proactively ahead of time. Next slide.

As a reviewer unfortunately nobody really wants to get reviewed so I have a very different experience doing PAL consults versus doing mandatory second opinion reviews. I work very hard to have every review end on a positive note with somebody having learned something or come with some new treatment ideas. But you can't please everybody and sometimes people just thought it to be a hassle. That was the end of the slides.

Now really the topic that was being talked about…I want to let you all know what's been going on with those two programs. The topic of issue being subject abuse of stimulants. Just last week in the PAL program I talked to…this is just one of the examples of academic detailing we do. I talked to a primary care provider who said, "Gee, this kid who is 17 years old and is a nuance ADHD and

would like a script for this," and I said, "Do you realize there really isn't any such thing as new onset ADHD at age 17?" And so we had a good discussion about that and I steered them towards the non-stimulant way of thinking about things and really truly validating what's going on and chances are there's actually been some studies about this. If somebody has ADHD and is a substance abuser and is really just sort of newly looking for a controlled substance if you put them on what should be an effective ADHD treatment like Strattera or Wellbutrin they tend to stop taking it because it's not fun. So there's a lot of other interesting things about substance abuse for ADHD people. We know if somebody has ADHD they actually have ADHD and they are at higher risk for becoming a substance abuser as it is. To the best of our knowledge if somebody is using stimulants appropriately that actually reduces their chance of becoming a substance abusing adult if they are using it appropriately. There's some other public safety things too. So the ADHD teenager behind the wheel of a car…you actually want them on a stimulant as opposed to not on a stimulant so they don't run into somebody. So there's good data behind that.

It's a complicated issue and I'm curious what the group has to say on this. I just wanted to let you know about what we've been doing.

Vyn Reese: Hi. It's Dr. Reese. I was curious; I've seen this in the literature. I'm an internist so I don't see a lot of pediatrics, but the…so the idea is that if an ADHD kid is not treated for ADHD they have a higher risk of becoming a substance abuser later?

Bob Hilt: Correct. Actually all…if you have a diagnosis of ADHD whether or not you are treated you're at a higher risk of becoming a substance abusing adult and it seems to be reducing the risk if you in fact are being properly treated.

Vyn Reese: So if you're treated with a stimulant as…and you have ADHD then you have a lower risk of becoming a substance abuser later?

Bob Hilt: Right. And it's essentially…it makes logical sense that one of the core problems of ADHD is being impulsive. And so the stop and think before you do something actually has something to do with illicit substances.

Vyn Reese: Okay. Any other questions from the committee?

Patti Varley: This is Patti Varley and everybody should know I work with Bob in the same exact building, in the same exact hall and I've been a big defender of the second opinion and Bob will tell you I am second opinion probably statistically up there.

Bob Hilt: All of the reviewers get second opinioned as well.

Patti Varley: Yes. And so my question to you in that this recently happened, as you know, is the disruption of care to a patient in regard to awaiting the second opinion thing. And this sort of writing it's a crisis kind of thing um that only works if I know ahead of time that they're going to have a stop.

Bob Hilt: True.

Patti Varley: So in the case we just had which was a case that, and life happens, even in the same building where my second review took a while my concern had only to do with not getting second opinion, but with the access of medication for the patient. So is there a way of looking at that, that there is…because I was never asked by the pharmacy, interestingly, myself about saying, "Is this a crisis and do they need it?" I just kept getting the paperwork saying, "You need the second opinion. You need the second opinion." Because I support the system but I obviously still am a clinician whose patients are mad at me because they get the word from the pharmacy that I haven't responded when I have. I kind of am feeling a need to kind of work this through for the group because the intent is good, the program is good, but these glitches make it less appealing I think. So I'm just wondering your thoughts on that because that's a real example we just had.

Bob Hilt: I think the ultimate way to improve this would be able to say, "If you're the prescriber and you have somebody who you know is a Medicaid client," because it's on your little fee sheet or whatever, and you're writing a script and you say "oh yeah I think it's going to get flagged for review". To be able to fill something out and send it in at the time and just take the end run out of all of this paper going back and forth stuff, the problem is again is I had it explained, even if we set up the review, if you call our review program and say, "Hey, I know this is going to get flagged, can we just sort of set this up and do this ahead of time?" even if I fill out the piece of paper and say, "Okay, we have a review ready to go, there's nowhere to attach it". So that's a fatal flaw of the system as it is right now and I know there's all this stuff about Provider One changing things. I don't know if that's a potential that's going to get changed with implementation of provider one.

Christine Klingel: Hi. This is Christine Klingel. I'm a pharmacist and maybe people at HRSA could comment on how that would get approved if you do have a patient in crisis? Is it similar to the anti-psychotics? Because actually I had a case last Friday the exact same situation, I didn't know that was the reason why their olanzapine was getting denied for a five-year-old child at a higher dose. The psychiatrist didn't know either. And so we ended up having to sample and everything. And I'm like, "Oh this would have been great to know last week that we could actually get the child the medication without having to use samples."

So neither he nor I knew about this option of actually having the patient receive the medication if they were in crisis.

Charles Agte: This is Charles Agte with Medicaid and what I can tell you in regard to a couple of the things that have been mentioned is part of the requirement that we have that even if you get a review in advance the client will still hit a stop at the pharmacy and the pharmacy will need to call and that's because the way our system is set up we don't necessarily know what the pharmacy will be filling your order with. Since the system is product based as you know there are multiple sources for most things. Even if there was a single source drug you're writing for drug X at 30 mg. We don't know that maybe the pharmacy that week is out of 30s and fills it with two 15s. So without actually having a stop at the pharmacy and have them call we don't know what to authorize in advance. So we may have the clinical opinion in advance. We could have everything lined up and know if a call comes in on this child here's what has been approved in advance. But we still have to have that call from a pharmacy to know what to approve at that point in time.

And then the other aspect as you said child in crisis is something we recognize for nearly any mental health related drug and the additional factor there is because I believe Bob had in one of his slides the possibility that someone goes without medication because we didn't have it on file. When we're contacted for the authorization we will continue anything that a client has. If we get the information that it is a continuation of a previous therapy we will automatically approve that if that information comes to us.

Patti Varley: And this is Patti Varley and that in theory is exactly what I was hoping would happen. But that I will tell you in reality is where it does not always happen. So in this case, this was a refill prescription for a patient, it got stopped needing a second opinion, which again I don't have an issue with, but in the meantime even though it was a continuation the prescription was not allowed to be filled and again if it's a Thursday evening and I'm not back in the office until Monday that patient goes that weekend without the medication. And for me…so can the parent say it's a crisis or do I need to say it's a crisis? Because obviously it's going to be a crisis.

Chuck Agte: If the information comes to our pharmacy line they are instructed to accept the statement of child in crisis. They don't ask whether the doctor wrote it on the script, they don't ask whether it's the pharmacist's opinion or whether it's the family's opinion. If they are told that this is child in crisis we honor that. Or at least we're supposed to. As you point out I, you know, without statistics in front of me I can't say it definitely but the glitches as you say generally are the exception rather than the rule. And as a rule most of the time the problem works

without a hitch. It's not perfect, there will be glitches sometimes, but I want to be careful about representing the process with the exception.

Patti Varley: And this is Patti Varley again. And that is the interesting thing. It's usually an idiocratic thing where a particular pharmacy or even at times a particular pharmacist's interpretation of the rule is what these glitches occur in. It's not the program as a whole.

Christine Klingel: Christine Klingel speaking up for pharmacists it might just be an ignorance of the rule too. I had no idea. I don't know if I'm an ignorant pharmacist or not but I don't want to distinct that openly on the mike, but I would think, you know, if that could get communicated again, I've asked before, you know, for how pharmacists can go about that, you know, calling and stating that, you know, if a patient is in crisis this can get okayed. I haven't seen anything with that information before. So it's good information to know.

Vyn Reese: Thank you. I'd like to have some stakeholder input at this point. Representative Hurst would you like to speak?

Christopher Hurst: Thank you very much doctor. I'm state representative Christopher Hurst from the 31st legislative district and I'm also the chair of the Public Safety Committee in the House. I'd like to thank this group very much. I'd like to thank the staff and some of the folks we've had some discussions with in the last month. There have been very, very good discussions and the presentation today, and taking into consideration kind of goes into what we were talking about a little bit which was what about the drugs that are diverted and then what's the impact of those? I know that it was a question before this body to say how do we take that into consideration? Should we consider those type of fiscal impacts? And the fact that this discussion is happening today is very good. I think the presentation was about exactly as I expected it to be. I also spent 25 years in law enforcement and all of that as a detective and 14 years of that I actually spent in narcotics law enforcement and was a commander of a very large task force. The initial data showing that somewhere between 8 and 10% of college age kids using stimulants about half of which is Ritalin is in and of itself if you extrapolate that into the general population numbers a pretty large group and it's fairly consistent with what data I've gotten recently from the Department of Justice and talking with some of the Department of Justice folks. But the really intriguing thing was the subset, which is also something we've known for a long time and that's that…it was a question that was brought up earlier than 70% of the people that abuse stimulants in that age group also use depressants. And I think the fundamental question was why does that occur? I actually know why that occurs and from interviewing tons and tons of people it comes from the fact of enjoying the use of the stimulant of course of which half of it is done for studying purposes and I think performance enhancement wasn't addressed. It was a very good point. A

lot of people missed that because in a short-term situation it is quite valuable as a tool for that and a lot of people have figured that out in that age category. But the problem is you use these substances and then you can't sleep. So what we've found is you have to medicate to sleep because you get yourself in this perpetual state of…I wouldn't call it anxiety but it's this heightened sense where then you need to medicate and ultimately in some point in time there are two fundamental problems. I will conclude quickly here. But there are two fundamental problems. One of them is what drug do you use? What's available? And then the method by which you use it. And that's been another factor that's changed dramatically. When people were predominantly injecting drugs we knew what the outcome of that was. Then when people switched over to other forms, in particular inhaling the drugs, whole different story. But if you're injecting the drug, snorting the drug, and then take it one more step when people figured out that they could take these drugs, put them back into their base form in the instance of an illegal substance like cocaine and smoke it how quickly it's metabolized and how much more addictive it is.

I'll just give you one quick antidotal story. I was interviewing a guy, most of you are doctors I believe on the board here I would assume.

Vyn Reese: We are pharmacists and PAs and nurse practitioners too.

Christopher Hurst: Very good. Yes. But you'll understand this question which is what is your likelihood of surviving a full cardiac arrest? If I had a full cardiac arrest right now, and even with doctors here, what are my chances of surviving that? If there's Medic One close by about 20%. If we don't have a Medic One system maybe closer to 10%. But I interviewed a guy in jail one day and it was a young person and he had had four full cardiac arrests from smoking crack cocaine and I was talking to him and I said, "Daniel, do you realize this is going to kill you? You're very fortunate to have gotten to this place." And he goes, "I know. I know it will kill me. I know I will die from this." And he goes, "But I can't explain to you what it's like." He goes, "It's the only thing I think about when I'm awake." And that's the problem with stimulants is the addictive factor. And what's happening with these drugs today is people rather than ingesting them a lot of them are breaking them up and smoking them and of course that's the problem also with the depressants. It's the method by which you use them that dictates how quickly you get addicted.

So what I want to leave you with…I want to thank you for looking at this, but what I want to leave you with is what is the cost? Now I got a call this morning from the governor's office. That's not a great way to start your morning. Have the governor call you up and saying, "I need some answers on something," because no one is happy right now that's working in government or being a representative. And the question was, "Chris, you're the chair of the committee.

We gotta figure out what we're going to do with this gang problem in the lower valley. We had a ton of shootings in the last few weeks and of course drugs are fueling the gangs, that's where the money comes from for gangs. And you gotta come up with some solutions here and we gotta get out on the street with these right now." I have to tell you that I'm getting more and more pressure from citizens and from groups over this prescription drug issue insisting that I come up with tougher laws. I'm trying to resist that and here's why. We don't have any more money to put people in more prisons. It just does not exist. The funds are not there. And if this continues at its epidemic rate which you're hearing about I'm going to be stuck with people demanding that I pass longer sentences, tougher things, and the solution has to lie in these other areas which is controlling diversion, educating people better, having things like drug corp. We made enormous progress here recently by having the first veterans court for soldiers returning back who are having an exponentially huge explosion in different types of crimes and substance abuse.

Just started down in Thurston County but we can't afford to allow people…or we can't afford to ignore that when a person gets to that level and they can't get the drugs anymore they start to use the illegal drugs. I've known for years and the Justice Department will back this up but I can certainly give you the data. 70% of all crime committed in the country, 70% of the crime committed in Washington State goes to pay for illegal drugs. The way you get to those illegal drugs today is starting to become more and more and more by the abuse of prescription drugs. And although we know there's been a problem with depressants for a long time, and in fact you're more likely to see somebody die today, a young person, of just the drug OxyContin than you are of an automobile accident of anybody of any range…age range in Washington State today. We have to measure what is the cost to society and then ultimately the taxpayers.

So as you make your decision about the generics for policy, and I realize very well from our last discussion, that a person that's monitored by a physician using Ritalin or another drug, a non stimulant drug, those abuse mates may be similar in those clinical studies. What I really implore you to consider is how many people is 8 to 10% of the college population and then divide that in half of the people that are using Ritalin. Look at the raw numbers and extrapolate that out as to how many students that is and say, "Where are these drugs coming from," and the end result, if there is a cost to society that outweighs the cost of a non stimulant drug, and I think there's been some great presentations here about when you give them a non-stimulant drug they stop using it because it's not fun. They're not getting what they're looking for. I really will implore you to consider as part of your deliberations, please, I'm asking you, what is the cost of those people to society, to our criminal justice system and ultimately to you and other people who want to use the medical system whether it's basic health or any other portion.

So please don't do something that saves a few dollars or even a few hundred dollars that ultimately puts somebody in my hands where we have to spend now $32,000 a year to incarcerate them. We can't afford to do it anymore. So let's look at this analysis and I thank you for considering this. I'm going to continue to work with folks. But let's make sure that what we can do, and I know there's many different mechanisms, what we can do to have fewer people abusing these drugs, stimulant drugs, and the opiates. I urge you to realize that that is a part of the deliberations [inaudible] and I want to thank you very much for this presentation today and your time. If you have any questions I'd be happy to answer them.

Vyn Reese: Thank you Representative Hurst. Any questions?

Barak Gaster: This is Barak Gaster and I'm just kind of thinking about sort of legal tools that we can use to address this problem and the DSHS program that allows physicians to get a report of all of the Medicaid prescriptions that a patient has had filled in the last year, to me it has been…I've had terrific success with that. That has been a really valuable program. But the big hole has always been, "What about the prescriptions that people are filling that they're not sort of charging to DSHS?" And so then that sort of begs the question of, "Why couldn't there be a statewide program like that which linked all pharmacies together that, you know, that sort of bumps up against sort of HIPAA patient confidentiality issues. I think the way that the DSHS program has gotten around that is by having a patient actually sign a consent form sort of allowing the doctor to sort of request that information. Partially it sort of gets around the patient confidentiality issues, but it does sort of bring to my mind, in terms of a statewide sort of legal solution to try to solve this problem is why couldn't there be a not Medicaid specific report available about all the drugs that a person has gotten filled.

Christopher Hurst: That's a very good point and what's interesting is we've pretty much done that with sudafedrin now. So what we have done with a non-prescription drug, which of course some people wanted to make a scheduled drug, which I didn't really think made a whole lot of sense considering all the other problems we have. You go in, they scan your driver's license now because most of the stores have actually gone to a scanning system, and what it does is…when a person's going around and buying the multiple maximum amounts of sudafedrin to make methamphetamine it does, it flags it immediately. The computer says, "Nope. You've already bought too much of it within a period of time." I don't think we need to violate patient confidentiality. I think if the system is linked and simply a red flag comes up it doesn't have to release information. It can just be a no fill and then maybe there's a mechanism whereby somebody from a medical point of view says, "Well, you now are dealing with this patient and the fact that they have…" because this is very common. I know people that are getting

prescriptions from 6, 8, 12 doctors are a time. We do need to improve the system and I think that it doesn't have to share confidential information, but if there's a block that says there is something wrong here that allows then doctors to communicate, I think physicians communicating for the welfare of their patients I would be hard pressed to imagine that that is an impediment to HIPAA but if it is the legislature would be more than happy to remove that impediment if that's what is necessary.

As we just did recently the session before last we made a major modification to the HIPAA laws when we said that police and doctors and corrections officers on the street now can freely exchange information without the permission of the person if that person's interest, safety, welfare could potentially be at harm within a reasonable period of time. I think with drugs you can make that argument and use the same principle that we just passed into law.

Barak Gaster: This is Barak Gaster again. Does anyone in the room know of programs like that that other states are using?

Cathy Williams: Barak, this is Cathy Williams, Board of Pharmacy. What you're talking about is a prescription monitoring program. Could you please address why we don't have one in this state? That is exactly what's needed. Not just the sudafedrin monitoring but a prescription drug program that was approved by legislative statute, funded through the attorney general's office and yet not in place.

Christopher Hurst: You know things that happen in the…here's what happens in the political world. Um, the pressure has been on methamphetamine partly due to the fact that Washington had become the methamphetamine capital of the United States and in particular Pierce County had become the methamphetamine capital of the world interestingly enough. So here's the problem I was trying to speak about earlier, which is why prescription drugs and the abuse of Ritalin is a problem for me because people come and pound on my door and when the newspapers scream enough and when enough people come down and scream and yell and say, "By God we're going to have this. We don't care about anything else." It's easy for me to say there are more important issues. If we were to prioritize this with other issues of substance abuse, for instance the program you're talking about, logic would have dictated that it was a much bigger problem. However, because methamphetamine was what was getting all of the stories, the exploding labs, burning down houses, people dying, toxic chemicals in their backyard, that's where the legislature acted. I guess part of the answer to your question is because that is where the public pressure was and politicians, if they don't respond to that they get voted out of office. Now that's a reality. That's how we govern ourselves. But I agree. This is something that should be done. Fundamentally it brings us back to my very first question though, which is I'm trying to get you to understand the pressures that I'm going to have to increase

sentences for prescription drug abuse when we need to realize what the cost of that is compared to the cost that we might save by keeping stimulants out of the hands of people.

So I'm really asking you in essence to say there should be a fiscal analysis as part of the deliberation. Now I'm not saying don't use it, not at all. I think it's perfectly good to use, but I think there are very, very…we should be very, very cautious to realize that in many, many cases it won't be a problem. But in the cases that it is one individual person can result in a cost to the taxpayer of hundreds of thousands of dollars.

Vyn Reese: This is Dr. Reese. I have one comment. One concern I have is that we really need to monitor what patients are doing and if they're getting multiple prescriptions. And it's really important that we have a statewide system.

Christopher Hurst: I agree.

Vyn Reese: I think that would cut out a lot of this abuse and in opiates…and what's happening with Medicaid patients it's really helping. But it's got to be done statewide with all pharmacies in the state for controlled substances. And so unless you do that you're just whistling in the wind. You've got to make that commitment and get that done at the state level.

Barak Gaster: This is Barak Gaster. I'd like to make a motion that this committee makes a formal recommendation to the…I guess who would we be making it to?

Woman: The governor.

Barak Gaster: Yeah. That we have a statewide pharmacy monitoring program.

Duane Thurman: This is Duane Thurman. This is not grill the legislature meeting. I think this is a good conversation. I think that your recommendation should be to the department through Medicaid and then we will take it through the channels as appropriate with the governor's office.

Barak Gaster: That is who I would like to address it to.

Christopher Hurst: People grill me all the time.

Patti Varley: This is Patti Varley and it's very interesting because from where I sit seeing from both sides what Cathy is saying is exactly what you're saying from different angles, which is that we, as prescribers, have a responsibility of limiting the access of excessive medications out there that are abusable and what she said is that there was this vote to approve that whether they were Medicaid or not,

whether they were using their Medicaid or not, because we also know that they fill things on Medicaid and then they fill it with something like the money they got from selling the ones they got on Medicaid.

Christopher Hurst: Seriously? Does that really happen?

Patti Varley: And that this issue of I have no way of knowing unless somebody tells me that this patient is filling multiple prescriptions. That's really the same thing, supporting the same idea which I'm responsible for the prescriptions I write but I'm only as good as the information I have about what is happening out there. And if I don't have a way of being informed like I was by this wonderful pharmacy that said, "What a minute. We're not filling this script on this patient. They should have some." That allows me to do my part which is to limit, which I've done not giving them anymore, but without a system that informs me of that in my busy day-to-day life it becomes very challenging and to be honest there have been more than one example time in my career where I've suspected it but I haven't been able to track it down because they are very savvy.

I was telling the person next to me I had a family I knew in my heart something was wrong, but I couldn't get my finger on it until they made an error. They had stolen prescription pads from several offices. They were filling mine at Rite-Aid, they were filling another one at Walgreen, another one at Costco and she screwed up and she brought a prescription and they called me and said, "How come Dr. so and so is writing for the same med you are for this patient?" And I went, "Ta da." And I put that system in place where all the pharmacies were notified and sure enough we found out about it. But if there was a system that every time that patient's name had a prescription filled and when there were duplicates or things that would help us to limit it. But it needs to be a team effort where all the systems are working together to make it doable.

Christopher Hurst: Sure. Those are very, very good points and very important and also you've illuminated what of course I saw, which was people with stacks of prescription pads that simply made a doctor's appointment when they were less careful with them and would take those right out the door and of course those were like gold. Those are a currency out of the street. But back to the fundamental question is if there's an opportunity with people once again it's more expensive in some cases. The ultimate cost to society being less is not to lose focus of this issue of what is the fiscal impact of stimulant drugs and of course now I think it's great that you understand that 70% of the people that are abusing Ritalin are also abusing some type of a narcotic, which of course at some point in time turns to street drugs and the cost being enormous.

So the fact that you're having this discussion in this deliberation I have to thank you very much because I was concerned and I appreciated you getting me in on

short notice last time and maybe I was a little clumsy but the fact that we're going to have an opportunity to continue to look at this and say the fiscal impacts of that are a matter for consideration is very important to me. So I want to thank you again and I hope I haven't taken too much of your time.

Vyn Reese: Well you're a little over your three-minute limit, but given that you're a legislator we'll let you do that. Now everybody else we're going to hold strictly to that. You have a special dispensation today.

Christopher Hurst: Thank you for allowing me to be here. I do want to say that the response of folks that I've talked with and their willingness to have these discussions and the group to look at this means a great deal to me. So thank you very much.

Vyn Reese: Thanks for coming.

Susan Rowe: This is Susan Rowe and Representative Hurst I did hear you mention the generics first. I'm not sure that's applicable to this discussion necessarily because it's always been my understanding that generics do not have the street value that a brand name does. So I think…I think we're all in agreement that we want to monitor what our patients are getting. I think the generics first is a separate issue.

Christopher Hurst: I guess I'll have to disagree with you on that point. I had discussions here in this last week with some of the colleagues that I used to work with in the drug enforcement field and specifically the Tacoma office of the Drug Enforcement Administration with the Justice Department. Of course they base their statistics on national statistics but then they also look at the trends on a regional basis. So we have the western district of Washington is a unique region in and of itself in which the Department of Justice keeps statistics. The value of those drugs is the problem. It has gone up so much and this is why we are seeing so much diversion.

Drugs that not that long ago used to sell for $2.00 or $3.00 per tablet we thought when it got to $8.00 we were like, "My God, who in the world is paying $8.00 for these things?" Two days ago I called those folks up and I said, "Can you give me your best feeling in the last month or two the value of some of these drugs today?" And they said, "OxyContin right now…baseline cost on OxyContin," hang on a second "is $80.00." And I said, "Can you give me an idea what people are paying for some of the generic stimulants?" And he said, "The sky's the limit. It's like the market for gold going out of control." And as we've seen this explosion on the campuses of the use in that group the price has gone up so much. If a person had a prescription for a stimulant years ago it wasn't worth their time and trouble or the danger of selling it to someone else because you were going to do 21 to 27 months in prison for one delivery of a controlled

substance. But today if you're talking about things that used to sell for $1.00 that today can be selling for $60.00 to $80.00 per tablet there's a great incentive to get it in that aftermarket because you can buy other things, especially for younger people. So the incentive to abuse the stimulants, which didn't exist when it was only worth a buck has changed dramatically with cost.

Vyn Reese: I want to comment on one thing that we've talked about in the committee quite a bit. Okay? I think you have to be very careful if you're talking about a kid with ADHD who really…a stimulant has been shown to be the most effective drug for that kid.

Christopher Hurst: Certainly. I agree completely.

Vyn Reese: And if you don't treat the kid with ADHD they have a higher risk of becoming…having problems with drug addiction later.

Christopher Hurst: Absolutely.

Vyn Reese: And the non-stimulant drugs are less effective and in some cases more dangerous and more expensive. So you're telling us that if…you can overreact to this and say, "Okay, no kid gets a stimulant drug."

Christopher Hurst: I agree. Absolutely. No, no, no, and that is not…

Vyn Reese: Then what happens down the road is you have many more problems with addiction and you put people on drugs that may be dangerous for them that are much more expensive for the taxpayer. So you have to be able to back…

Christopher Hurst: Let me make it very, very clear. I'm not advocating for the non-use of stimulant drugs at all. That is not what I'm here at all suggesting by any stretch of the imagination. So let me be very, very clear. I'm not saying that you should ban and not use these. I think they are a very effective drug and I will agree that the behavior, the compulsive behaviors that this treats, untreated will lead to all types of behavior which many times will become criminal in nature. That's something we've certainly seen. So I'm not saying that these are not drugs…I'm not saying these are drugs that should never be used. I'm saying that my concern is too many of them being used and the doctor not having the proper level of discretion at the time they are prescribing them to have an instinct about, "Is this is a family that can monitor the use of what now has become a valuable commodity?" But by no means am I suggesting that they should not be used and in fact I think if you did take them off the market completely and they were not available for use you would be creating a real nightmare and some of these people's lives. So I'm not at all opposed or disagreeing with that. I'm saying that in many, many cases the abuse potential may be higher than you think and the ultimate cost of that is

significant. I'm not discounting the value it has in saving or helping one person's life that might otherwise fall off the wagon socially or criminally from a societal point of view.

Vyn Reese: Okay. Any other questions?

Duane Thurman: This is Duane Thurman. Just to clarify Dr. Gaster's request if you want to make a recommendation you're currently sitting in your capacity as the Drug Utilization Review Board for Medicaid and you would be making it to that agency, which is complicated at this point because our new HCA administrator is the former Medicaid Director, Doug Porter, and so if you want to make that recommendation feel free to do that. It will go the department. It's an executive level branch, he's appointed by the governor and we will make sure that it goes through and is heard appropriately when this issue will inevitably come up again in the legislative session.

Christopher Hurst: I'm sure I'll be hearing from them.

Vyn Reese: So Barak do you want to make your…formally make your…

Barak Gaster: Yes. I'd like to make a motion that the DUR Committee makes a strong recommendation to Washington State DSHS that the DSHS only reporting program for 12-month prescription history is not sufficient to adequately protect Washington State Medicaid clients and that DSHS should advocate for a statewide prescription monitoring program.

Vyn Reese: I'll second that. All those in favor say, "Aye."

Group: Aye.

Vyn Reese: Opposed, same sign. It's passed.

Christopher Hurst: One again I thank you for your time and hearing me out again today.

Vyn Reese: Thank you for coming and for your interest. Other stakeholder input?

Man: I will adhere to my three-minute limit.

Vyn Reese: Will you identify yourself and who you are affiliated with?

Bill Struyk: I do. Bill Struyk, Johnson & Johnson. Two things with respect to the prescription drug monitoring program. One, it is on the books currently. It was passed in 2007 as part of the Blue Ribbon Commission on health recommendations. So it was being implemented. In 2008 the funding was pulled

from the program. So what you have is a program that's unfunded. I serve on Attorney General McKenna's Prescription Drug Task Force and the prime agenda item on that task force is the funding of that prescription drug monitoring program. So you're…the reality of which you speak and the architecture and funding are being looked at as we speak. I wanted to make you aware of that.

Vyn Reese: Okay. Thank you.

Barak Gaster: Thank you.

Vyn Reese: Any other stakeholder input? I have a Helen Nilon, Mental Health Action. Is she…no? Okay.

Nancy Fisher: This is Nancy Fisher at the Washington State Health Care Authority. I would just like to bring to your attention that…whether this is timely or not is to bring to people's attention if they do not know that the federal government is looking at a way to do a prescription drug monitoring program across the states and so it will all be coordinated. So this is very timely. I know the government moves slowly but one of the things, part of this health care reform is to get something in place within the next five years.

Vyn Reese: Let's hope so. Any other discussion?

Jason Iltz: This is Jason. I just want to point out, you know, a prescription monitoring program we've talked about how that could identify abuse and overuse but the flip side is also true. If we look at adherence or in particular non-adherence, you know, as Senator Hurst mentioned our jails are being filled up with crimes and what not. If we look at mental health just as a general category, you know, when crimes are committed by those particular individuals it's typically because they are non-adherent to their medications. So, you know, if that monitoring program could also look at the flip side and identify those gaps in therapy somehow that would help that end point that he keeps mentioning as well.

Vyn Reese: And this is Dr. Reese. As was said earlier it's very important in drugs like diabetes and asthma that patients take their medication to avoid complications from those diseases. It would be nice to know if they were actually taking their drugs in which often they don't even when they have access monetarily to them.

Barak Gaster: This is Barak Gaster. Before you leave, Dr. Hilt, I was wondering if I could ask a quick question of you. I also am a general internist and so I don't have a lot of sense about how ADHD treatment happens in the pediatric population. So I was wondering if I could get your thoughts on just a guess at what percentages stimulant starts among kids are actually done by PCPs as opposed to psychiatrists?

Bob Hilt: Oh. The majority…easily the majority of stimulant starts are by PCPs rather than mental health specialists. ADHD has really moved very firmly into the primary care arena in child primary care. I think the pediatricians have pretty uniformly adopted this in the family practice committee, pretty heavily adopted. Because I interact with a lot of providers around the state I do talk to some people who are family practice providers that say, "Yeah, I'm still a little uncomfortable with it." But if they see a lot of kids pretty much they've adopted this into their practice.

Barak Gaster: So when you say a majority do you mean 60% or 90%?

Bob Hilt: 85, 90 I would guess.

Woman: There is a shortage of child psychiatrists and this is a trend that you see across the country. So one of the things, I am a pediatrician, is that one of the top things that you learn to take care of is ADHD right behind asthma.

Barak Gaster: Yeah. This is Barak Gaster again. From my perspective as an adult provider it's almost impossible to find a psychiatrist that will help me in making a diagnosis of ADHD in an adult who previously has not carried that diagnosis and so I'm…so it is interesting to think about how among pediatric providers they have felt that they have sort of gained the confidence about doing the diagnosing of ADHD and how difficult…how much more difficult that is among adult providers…providers of adults. And it's gotta be just because the numbers that you see are so much lower. There probably are…there are certainly adults who have undiagnosed ADHD out there, but the numbers are so much smaller than the diagnoses that are made among the pediatric population.

Patti Varley: And Barak, this is Patti Varley. I would say too if you look at the diagnostic criteria which are child oriented. If you look at most of the valid and reliable assessment tools they're child oriented. So I would absolutely say that a new…a new diagnosis in an adult is also…has its challenges above and beyond the pretty standard regulatory diagnostic criteria in children. So that's…you multiplied into an arena that's much more complicated along with drug seeking behaviors.

Deb Wiser: This is Deb Wiser. I think the other issue as a family doctor is children who have been diagnosed with ADHD and treated for a number of years entering into the college realm where there is more abuse around them and ability probably to use those medications for other people. Deciding when to stop and trying to trial these folks off of the medication and not having a whole lot of cooperation with wanting to do so.

Vyn Reese: Any further discussion or questions? Now also on the agenda is Victoria Roberts.

Man: She's not here.

Vyn Reese: She's not here today. Is there any other further presentation that you'd like to make to the committee?

Man: Not at this time.

Vyn Reese: Okay. So that concludes our meeting then. Oh yes, and one of the things that we talked about earlier is we'd like to have the PPIs presented at the next Drug Utilization Review Committee. So we need to have that work done and on the agenda for our next meeting. So that would be in October. But the PPIs need to be reviewed in a drug utilization review format especially given the drug interactions that we discussed earlier on the P&T Committee. So that's something that we really need to look at.

Chuck Agte: Dr. Reese, we have taken note of that as a topic for next time around. I would like to ask, because there was particular concern around the potential drug/drug interaction. Is there any other specific concern you would like to see in regard to the PPIs that's not being [inaudible] within the P&T format?

Vyn Reese: They're a pretty static group except for that drug interaction which is a major concern at least…I mean to the internists and family practitioners. We all have our own little groups here so...but we'd definitely like to review that at a later date at the DUR.

Deb Wiser: This is Deb Wiser. I think with the PPIs there are some other interactions as far as absorption of other medications and I don't know if we're going to be looking at interactions with PPIs. I think they are…

Vyn Reese: There's also a concern with…there is one other…you're right. I should…we should broaden that a little bit. There's a concern about PPIs and absorption of calcium and Vitamin D and osteoporosis too. That's another drug interaction. So if we could look at that at the next DUR it would be great.

Chuck Agte: We will bring it back to you.

Vyn Reese: Any other comments before we adjourn? Okay. Then we are adjourned. Thank you.